

AD_____

Award Number: W81XWH-04-1-0897

TITLE: Patient Race and Outcome Preferences as Predictors of Urologists' Treatment Recommendations and Referral Patterns in Early-Stage Prostate Cancer

PRINCIPAL INVESTIGATOR: Thomas Denberg, M.D., Ph.D.

CONTRACTING ORGANIZATION: University of Colorado Health Sciences Center Division
of General Internal Medicine
Aurora, CO 80045

REPORT DATE: November 2007

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-12-2007		2. REPORT TYPE Final		3. DATES COVERED (From - To) 31 OCT 2004 - 30 OCT 2007	
4. TITLE AND SUBTITLE Patient Race and Outcome Preferences as Predictors of Urologists' Treatment Recommendations and Referral Patterns in Early-Stage Prostate Cancer				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-04-1-0897	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Thomas Denberg, M.D., Ph.D. E-Mail: tom.denberg@uchsc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Colorado Health Sciences Center Division of General Internal Medicine Aurora, CO 80045				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Abstract on next page.					
15. SUBJECT TERMS Prostate Cancer Health Disparities					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	75	19b. TELEPHONE NUMBER (include area code)

This is a nationally-representative mailed survey of 2000 urologists to (1) collect information about physician sociodemographics and clinical practice characteristics and (2) relate this information to treatment recommendations in three clinical vignettes. The vignettes allow for assessments of the independent effects of patient race, age, socioeconomic status, and tumor characteristics on urologist treatment recommendations in the setting of moderate grade, localized prostate carcinoma. Over the career development award period we have completed the survey and published six manuscripts. Key findings include the following. First, patient social vulnerability interacts with race to influence urologist treatment recommendations for radical prostatectomy. This is a novel finding with important implications for health disparities research more broadly. Second, the vast majority of urologists report performing fewer than 2.5 radical prostatectomies per month. Based on volume-outcome literature for radical prostatectomy, this raises significant concerns about surgical skill and outcomes. Third, a majority of urologists rate their own surgical outcomes as better than the national average, and a significant proportion provide erroneous information about comparative outcomes for major treatment modalities. Finally, for a hypothetical 77 year old patient who desires "cure," 85% of urologists recommended aggressive therapy when the patient has few concerns about treatment side effects and 68% of urologists recommended aggressive therapy when the patient does have concerns about side effects. These results are concerning because aggressive therapy confers little proven survival benefit but a high likelihood of side effects that should be avoided even in patients who profess little concern about side effects. This DOD Career Development Award has allowed the PI to establish a basis for making a transition to independent investigator. He is currently developing an R01 proposal to develop and evaluate a novel decision aid for multi-ethnic patients newly-diagnosed with localized prostate carcinoma.

Table of Contents

Introduction.....	4
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	5
Conclusions.....	6
References.....	6
Appendices.....	9-xx

Introduction

African American men with localized prostate cancer are about 25% to 30% less likely than non-Hispanic white men to be treated with radical prostatectomy (RP), even when adjustments are made for age, tumor characteristics, sociodemographic characteristics, and comorbid conditions [1-11]. Lower rates of prostatectomy among African Americans are intriguing because virtually all patients see urologists for confirmatory biopsies and for initial discussions about treatment, and because most urologists view prostatectomy as the best option for cure [12]. Although African Americans are more likely to fear surgery and distrust physicians than members of other racial/ethnic groups [13,18] – and may therefore refuse prostatectomy when offered – it is important to ascertain whether treatment disparities also emerge from systematic differences in clinician recommendations or, possibly, impaired opportunities for African American men to participate in therapeutic decision-making.

These possibilities are amply supported by evidence from other disease conditions showing that patient race and socioeconomic status can adversely influence physicians' advice and perceptions of patients [14, 15], that poor and minority patients are likely to receive lower quality health care [16], and that difficulties in doctor-patient communication are more apt to arise when the cultural and social background of physicians and patients diverge [17].

Body

Through a national survey of urologists, the goal of the proposed study is to assess whether differences in treatment recommendations and aspects of shared decision-making are associated with black-white disparities in recommendation for prostatectomy. The study has provided valuable descriptive information related to aspects of urologic practice in general, urologists' beliefs and attitudes about prostate cancer patients, and has characterized the sociodemographic and practice characteristics of urologists who treat large numbers of African American patients. The study results are being used to inform the development of patient and urologist interventions to improve the care of African American men.

Key research accomplishments

- We have developed, pilot-tested, and completed all survey mailings, collected responses, entered these into an Access database, and have carried out several analyses. A response rate of 66.1%, using Dillman survey methodology, is excellent. (See Appendix, page 9.)
- The following manuscripts, supported in full or in part by DOD funding, have been published (reprints can be found in the Appendix):
 1. **Denberg, T.D.**, et al., *Marriage and Latino ethnicity predict treatment in localized prostate cancer*. Cancer, 2005. **103**:1819-1825.
 2. **Denberg, T.D.**, T.V. Melhado, and J.F. Steiner, *Patient Treatment Preferences in Localized Prostate Carcinoma: The Influence of Emotion, Misconception, and Anecdote*. Cancer, 2006. **107**(3): 620-630.
 3. **Denberg, Thomas**, Beaty, Brenda, Glodé, L. Michael, Steiner, John F. & Richard Hoffman. Trends and Predictors of Aggressive Therapy for Clinical Locally Advanced Prostate Carcinoma, 2006, *British Journal of Urology* 98(2): 335-340.
 4. **Denberg, Thomas**, Kim, Fernando, Flanigan, Robert, Fairclough, Diane, Beaty, Brenda, Steiner, John, & Richard Hoffman. The Influence of Patient Race and Social Vulnerability on Urologist Treatment Recommendations in Localized Prostate Carcinoma, 2006, *Medical Care* 44(12): 1137-41.
 5. **Denberg, Thomas**, Flanigan, Robert, Kim, Fernando & John Steiner. Self-reported Radical Prostatectomy Volume Among Urologists in the USA, 2007, *British Journal of Urology International* 99(2): 339-343.

6. Hoffman, Richard, **Denberg, Thomas**, Hunt, William, & Ann Hamilton. Prostate Cancer Testing following a Negative Prostate Biopsy: Over Testing in the Elderly, 2007, *Journal of General Internal Medicine* 22(8):1139-43.
- The following manuscripts are in preparation:
 1. Analysis of urologist treatment recommendations for an elderly patient with moderate grade, localized prostate cancer – assessing the independent and joint effects of patient preferences for cure and treatment side effects. Manuscript under preparation. (See Appendix, page 58.)
 2. Analysis of urologist perceptions of radical prostatectomy outcomes. Manuscript under preparation. (See Appendix, page 63.)
 - Dr. Denberg presented his work related to reference 4, above (“The Influence of Patient Race and Social vulnerability on Urologist Treatment Recommendations in Localized Prostate Carcinoma”) at the 2007 Innovative Minds in Prostate Cancer Today (IMPACT) meeting in Atlanta. In addition, Dr. Denberg was selected to appear in a special publication summarizing 10 years of research accomplishments through the Department of Defense Congressionally Directed Medical Research Program in Prostate Cancer.

Reportable Outcomes

1. Race interacts with social vulnerability to influence urologist recommendations for RP. Because PCa tends to be more lethal in blacks, urologists may view such patients as good candidates for RP. However, black race may amplify perceptions of social vulnerability, heightening urologists’ concerns about poor surgical outcomes and follow-up. These findings affirm the importance of modeling interactions between race/ethnicity and other social variables in health disparities research. (See Appendix, page 17.)

TABLE 2. Urologist Treatment Recommendations: RP Versus XRT (n = 1205)

Patient Variables	RP % (n)	XRT % (n)	Risk Difference* (%)	Relative Risk [†]	P [‡]
Black	31.6 (194)	68.4 (419)	0.0	1.00	0.74
White	31.6 (187)	68.4 (405)	(-0.1 to 0.1)	(0.85–1.18)	
High vulnerability	26.8 (155)	73.2 (424)	9.3	0.74	0.0005
Low vulnerability	36.1 (226)	63.9 (400)	(4.1–14.5)	(0.63–0.88)	
Black, high vulnerability	23.9 (68)	76.1 (216)	14.4	0.63	0.05
Black, low vulnerability	38.3 (126)	61.7 (203)	(7.1–21.6)	(0.49–0.80)	
White, high vulnerability	29.5 (87)	70.5 (208)	4.2	0.88	
White, low vulnerability	33.7 (100)	66.3 (197)	(-3.3 to 11.7)	(0.69–1.11)	

*Risk difference: second minus first group receiving a recommendation for RP vs. XRT.

[†]Relative risk: first versus second group receiving a recommendation for RP vs. XRT.

[‡]Wald χ^2 level of significance based on full logistic regression model of patient race, social vulnerability, and race; social vulnerability based on interaction on radical prostatectomy versus radiotherapy.

RP indicates radical prostatectomy; XRT, radiotherapy (brachytherapy or external beam).

TABLE 3. Urologist Treatment Recommendations: Aggressive vs. WW* (n = 1313)

Patient Variables	Aggressive % (n)	WW % (n)	Risk Difference [†] (%)	Relative Risk [‡]	P [§]
Black	94.5 (623)	5.5 (36)	-1.9	1.02	0.41
White	92.7 (606)	7.3 (48)	(-4.5 to 0.1)	(1.00–1.05)	
High vulnerability	91.5 (590)	8.5 (55)	4.2	0.96	0.004
Low vulnerability	95.7 (639)	4.3 (29)	(1.5–6.8)	(0.93–0.98)	
Black, high vulnerability	93.8 (289)	6.2 (19)	1.3	0.99	0.10
Black, low vulnerability	95.2 (334)	4.8 (17)	(-3.3 to 11.7)	(0.95–1.02)	
White, high vulnerability	89.3 (301)	10.7 (36)	6.9	0.93	
White, low vulnerability	96.2 (305)	3.8 (12)	(3.0–10.8)	(0.89–0.97)	

*Aggressive therapy indicates radical prostatectomy, radiotherapy, or cryotherapy.

[†]Risk difference: second minus first group receiving a recommendation for curative therapy vs. WW.

[‡]Relative risk: first versus second group receiving a recommendation for curative therapy vs. WW.

[§]Wald χ^2 level of significance based on full logistic regression model of patient race, social vulnerability, and race. Social vulnerability interaction based on curative therapy versus watchful waiting.

WW indicates watchful waiting.

2. Among urologists who performed RP (89.1% of the sample), 37.3% performed ≤ 10 RPs/year, 46.9% performed 11–30 RPs/year, and 15.8% performed > 30 RPs/year. Academic and urologic oncology fellowship-trained urologists were, respectively, 41% and 27% more likely than private-practice and non-fellowship-trained urologists to perform a high volume of procedures. Of all RPs performed yearly in the U.S., only an estimated 46.1% are performed by high volume urologists. A significant proportion of urologists report an RP volume that may be associated with higher rates of cardiac, respiratory, vascular, wound-healing, and genitourinary complications. (See Appendix, page 22.)

Variable	Volume (RPs/year)			P*	TABLE 2 Bivariate predictors of RP volume (1170 in sample)
	1–10	11–30	>30		
Practice type					
Private	38.7	47.4	13.8		
Academic	13.7	39.7	46.6	<0.001	
Urological oncology fellowship					
No	38.2	47.7	14.1		
Yes	26.0	32.5	41.6	<0.001	
Hospital beds					
<300	41.0	45.8	13.3		
≥300	27.3	48.8	23.9	<0.001	
Years in practice					
0–9	35.1	49.2	15.7		
10–19	29.3	50.9	19.8		
20–29	40.4	43.1	16.6		
≥30	48.9	41.8	9.3	<0.001	
Metropolitan area size, no. residents					
<50 000	41.7	50.0	8.3		*Chi-square test for categorical variables.
≥50 000	36.7	46.2	17.2	0.045	

3. A majority of urologists claim that RP has lower long-term rates of impotence and incontinence than is supported by evidence derived from larger community/multi-institutional series that use patient-reported measures. A majority claim that their own rates of urinary and sexual side effects are lower than what is supported by the evidence.. Forty percent of all urologists, and 55% of high-volume urologists, believe that rates of cure are better with RP than XRT, but the existing evidence does not support this. A sizable proportion (20%) of urologists believe incontinence outcomes are better w/ RP than ECR — in fact, ECR has significantly better incontinence outcomes. A significant proportion of urologists manifest unsupported optimism about RP side effects in general, about their *own* side effect outcomes, and about the side effects and potential for cure of RP in relation to XRT. We found many of these patterns to be more pronounced among urologists who perform greater numbers of RP's. (See Appendix, page 58.)
4. In a vignette portraying a hypothetical, generally health 77 year-old patient with moderate risk (Gleason 3+3), localized prostate carcinoma, urologist recommendations for aggressive therapy were influenced to a similar degree by patient concerns about side effects and desire for cure. A high proportion of urologists recommend aggressive therapy despite the absence of a clear-cut survival benefit and even though the likelihood of treatment side effects is large. (See Appendix, page 63.)

Conclusions

The PI has successfully completed the work described in the original grant proposal. Publications in first-rate journals have resulted and additional manuscripts are in preparation. The PI is drafting an NIH R01 proposal to establish himself as an independent investigator whose topical focus includes treatment decision-making in localized prostate carcinoma, with an emphasis on reducing treatment and outcome disparities among African American men. Key components of the decision aid include attention to (1) anticipated life expectancy; (2) reducing the urgency for making treatment decisions; (3) attenuating feelings of fear; (4) addressing common patient misconceptions about prostate cancer and treatment alternatives; and (5) reducing the inappropriate effect of anecdotal influences on treatment deliberation. These elements go beyond the usual biomedically-oriented content of decision aids that focus on summary descriptions of treatment options and their associated probabilities of cure and side effects.

References

1. **Denberg, T.D.**, et al., *Marriage and Latino ethnicity predict treatment in localized prostate cancer*. Cancer, 2005. **103**:1819-1825.
2. Harlan, L., et al., *Geographic, age, and racial variation in the treatment of local/regional carcinoma of the prostate*. J Clin Oncol, 1995. **13**(1): p. 93-100.
3. Harlan, L.C., et al., *Factors associated with initial therapy for clinically localized prostate cancer: prostate cancer outcomes study*. J Natl Cancer Inst, 2001. **93**(24): p. 1864-71.
4. Hoffman, R.M., et al., *Racial differences in initial treatment for clinically localized prostate cancer. Results from the prostate cancer outcomes study*. J Gen Intern Med, 2003. **18**(10): p. 845-53.
5. Klabunde, C.N., et al., *Trends and black/white differences in treatment for nonmetastatic prostate cancer*. Med Care, 1998. **36**(9): p. 1337-48.
6. Lai, S., et al., *Radical prostatectomy: geographic and demographic variation*. Urology, 2000. **56**(1): p. 108-15.
7. Morris, C.R., et al., *Sociodemographic factors associated with prostatectomy utilization and concordance with the physician data query for prostate cancer (United States)*. Cancer Causes Control, 1999. **10**(6): p. 503-11.
8. Schapira, M.M., T.L. McAuliffe, and A.B. Nattinger, *Treatment of localized prostate cancer in African-American compared with Caucasian men. Less use of aggressive therapy for comparable disease*. Med Care, 1995. **33**(11): p. 1079-88.
9. Shavers, V.L. and M.L. Brown, *Racial and ethnic disparities in the receipt of cancer treatment*. J Natl Cancer Inst, 2002. **94**(5): p. 334-57.
10. Shaw, M., et al., *Changes in radical prostatectomy and radiation therapy rates for African Americans and whites*. J Natl Med Assoc, 2000. **92**(6): p. 281-4.
11. Wilt, T.J., et al., *An evaluation of radical prostatectomy at Veterans Affairs Medical Centers: time trends and geographic variation in utilization and outcomes*. Med Care, 1999. **37**(10): p. 1046-56.
12. Fowler, F.J., Jr., et al., *Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer*. Jama, 2000. **283**(24): p. 3217-22.
13. Shankar, S., E. Selvin, and A.J. Alberg, *Perceptions of cancer in an African-American community: a focus group report*. Ethn Dis, 2002. **12**(2): p. 276-83.
14. Schulman, K.A., et al., *The effect of race and sex on physicians' recommendations for cardiac catheterization*. N Engl J Med, 1999. **340**(8): p. 618-26.
15. van Ryn, M. and J. Burke, *The effect of patient race and socio-economic status on physicians' perceptions of patients*. Soc Sci Med, 2000. **50**(6): p. 813-28.
16. Institute of Medicine, *Unequal treatment: confronting racial and ethnic disparities in health care (Committee on understanding and eliminating racial and ethnic disparities in health care)*, B.D. Smedly and e. al., Editors. 2002: Washington, D.C.: National Academy Press.
17. Saha, S., J.J. Arbelaez, and L.A. Cooper, *Patient-physician relationships and racial disparities in the quality of health care*. Am J Public Health, 2003. **93**(10): p. 1713-9.
18. **Denberg, T.D.**, T.V. Melhado, and J.F. Steiner, *Patient Treatment Preferences in Localized Prostate Carcinoma: The Influence of Emotion, Misconception, and Anecdote*. Cancer, 2006. **107**(3): 620-630.
19. **Denberg, Thomas**, Beaty, Brenda, Glodé, L. Michael, Steiner, John F. & Richard Hoffman. Trends and Predictors of Aggressive Therapy for Clinical Locally Advanced Prostate Carcinoma, 2006, *British Journal of Urology* 98(2): 335-340.
20. **Denberg, Thomas**, Kim, Fernando, Flanigan, Robert, Fairclough, Diane, Beaty, Brenda, Steiner, John, & Richard Hoffman. The Influence of Patient Race and Social Vulnerability on Urologist Treatment Recommendations in Localized Prostate Carcinoma, 2006, *Medical Care* 44(12): 1137-41.
21. **Denberg, Thomas**, Flanigan, Robert, Kim, Fernando & John Steiner. Self-reported Radical Prostatectomy Volume Among Urologists in the USA, 2007, *British Journal of Urology International* 99(2): 339-343.

22. Hoffman, Richard, **Denberg, Thomas**, Hunt, William, & Ann Hamilton. Prostate Cancer Testing following a Negative Prostate Biopsy: Over Testing in the Elderly, 2007, *Journal of General Internal Medicine* 22(8):1139-43.

APPENDIX

Sample survey.....	10
Medical Care manuscript.....	17
British Journal of Urology manuscript (1)	24
Cancer manuscript (1).....	29
Cancer manuscript (2).....	36
Journal of Internal Medicine manuscript.....	47
British Journal of Urology manuscript (2)	52
Urologist treatment recommendations for elderly patient.....	58
Urologist perceptions of radical prostatectomy side effects.....	63

Appendix: Sample survey**University of Colorado Health Sciences Center**

Localized Prostate Cancer Research Group

SURVEY

Robert C. Flanigan, MD, Chair in Urology, Loyola University

Thomas D. Denberg, MD, PhD, Department of Medicine, University of Colorado

Fernando J. Kim, MD, Chair of Urology, Denver Health Medical Center, University of Colorado

1-

SECTION 1:

Vignette 1: Please consider the following information and then offer a treatment recommendation:

Patient: 77 year-old white male

Social: Married, retired furniture salesman, lives close to a major medical center, no transportation barriers.

Insurance: Medicare

Diagnosis: Localized (organ-confined) prostate cancer (TRUS=DRE;
No nodule)

Gleason grade: 3+3

Biopsy: 2 out of 12 cores on the left each had 10% tumor

PSA: 5.4 (obtained by primary care provider)

CT scan: No evidence of regional lymph node involvement

Bone scan: Negative

Prostate size: 30 grams

Family history of prostate cancer: None



AUA symptom score: 7 (i.e. mild urinary symptoms)

Sexual function: Normal erections satisfactory for intercourse

Comorbidities: Gout, on allopurinol and a daily aspirin. Otherwise healthy and active.

Patient concerns: Patient understands the potential side effects of all treatment alternatives.

He says, “cure is not as important as enjoying life – everyone has to die sometime.”

He also says, “I would not be greatly bothered by urinary leakage and could wear pads if I had to. As far as sex is concerned, my wife and enjoy it but could easily adjust to living without it.”

He is anxious to know your treatment advice and is willing to carry through with anything you recommend.

Given the following four options only, please indicate which one you are *more likely* to recommend (**mark only one answer**):

_____ Radical prostatectomy with optional nerve sparing

_____ A form of radiation: ____brachytherapy OR ____external beam

_____ Observation (or “watchful waiting”)

_____ Cryotherapy

In the year 2005, would you refer this patient to a medical oncologist to discuss or assist with treatment?

____ Almost certainly ____ Probably ____ Doubtful ____ Definitely not

Vignette 2: Please consider the following information and then offer a treatment recommendation:

Patient: 70 year-old African American male.

Social: Married, retired electrical engineer, lives close to a major medical center, wife is very concerned.

Insurance: Medicare

Diagnosis: Localized (organ-confined) prostate cancer (TRUS=DRE;
No nodule)

Gleason grade: 3+3

Biopsy: 2 out of 12 cores on the left each had 10% tumor

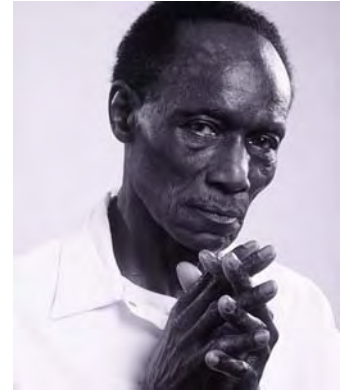
PSA: 3.2 (was 4.8 two years ago, by primary care provider)

CT scan: No evidence of regional lymph node involvement

Bone scan: Negative

Prostate size: 35 grams

Family history of prostate cancer: None



AUA symptom score: 6 (i.e. mild urinary symptoms)

Sexual function: Normal erections satisfactory for intercourse

Comorbidities: Essential hypertension on an ACE-inhibitor. Otherwise healthy and active.

Patient concerns: Patient understands the potential side effects of all treatment alternatives.

He says he wants a chance at cure more than anything but very much wants to avoid treatment that interferes with his sexual function.

He is anxious to know your treatment advice and is willing to carry through with anything you recommend.

Given the following four options only, please indicate which one you are *most likely* to recommend (**mark only one answer**):

☐ Radical prostatectomy with optional nerve sparing

☐ A form of radiation: ☐ brachytherapy OR ☐ external beam

☐ Observation (“watchful waiting”)

☐ Cryotherapy

If given the opportunity, would you recommend a form of hormonal therapy instead of, or as an adjunct to, your choice, above?

☐ Hormonal therapy alone (i.e. instead of above choice)

☐ Hormonal therapy as an adjunct to above choice

☐ No hormonal therapy

Vignette 3: Please consider the following information and then offer a treatment recommendation:

Patient: 66 year-old white male

Social: Married real-estate agent, lives close to a major medical center, no transportation barriers.

Insurance: Medicare

Diagnosis: Localized (organ-confined) prostate cancer (TRUS=DRE;
No nodule)

Gleason grade: 3+3

Biopsy: 2 out of 12 cores on the left each had 10% tumor

PSA: 5.7 (obtained by primary care provider)

CT scan: No evidence of regional lymph node involvement

Bone scan: Negative

Prostate size: 45 grams

Family history of prostate cancer: None



AUA symptom score: 12 (i.e. moderate urinary symptoms)

Sexual function: Normal erections satisfactory for intercourse

Comorbidities: Takes a daily aspirin, a statin, and a multivitamin. Had a “small” myocardial infarction five years ago with a single stent of his right coronary artery. He has excellent exercise tolerance and no cardiac symptoms. He walks about one mile a day.

Patient concerns: This patient understands the potential side effects of all treatment alternatives.

He says, “My urinary leakage is not a big problem – if I had to, I could wear pads.”

He also says, “my wife and I enjoy occasional sex, but we could easily adjust to living without it.”

He is anxious to know your treatment advice and is willing to carry through with anything you recommend. Given the following four options only, please indicate which one you are *most likely* to recommend (**mark only one answer**):

- ☐ Radical prostatectomy with optional nerve sparing
- ☐ A form of radiation: ☐ brachytherapy OR ☐ external beam
- ☐ Observation (“watchful waiting”)
- ☐ Cryotherapy

If given the opportunity, would you recommend a form of hormonal therapy instead of, or as an adjuvant/neoadjuvant to, your choice, above?

- a. ☐ No hormonal therapy
- b. ☐ Hormonal therapy alone (i.e. instead of above choice)
- c. ☐ Hormonal therapy as an adjunct to above choice

If (b) or (c) checked, above, please indicate preferred therapy (check more than one for combination therapy):

- ☐ orchiectomy
- ☐ LHRH analog (e.g. leuprolide, goserelin)
- ☐ anti-androgen (e.g. bicalutamide, flutamide)

SECTION 2:

Please circle your answers to the following questions:

1. For Gleason grade 8-10 localized prostate cancers, rates of cure are

- X higher with prostatectomy than radiation (external beam or seeds)**
X roughly the same with prostatectomy and radiation (external beam or seeds)
X higher with radiation (external beam or seeds) than with prostatectomy

2. With nerve-sparing prostatectomy, national rates of *any* form of long-term incontinence are:

<25% 26-50% 51-75 >75%

3. Different urologists treat different patient populations. Compared with the national average, your *own* surgical rate of long-term incontinence associated with nerve-sparing prostatectomy is:

lower about the same higher

4. With nerve-sparing prostatectomy and early oral phosphodiesterase-5 enzyme inhibitor treatment (e.g. Viagra), average national rates of long-term impotence (inability to sustain an erection for intercourse) are:

<25% 26-50% 51-75 >75%

5. Different urologists treat different patient populations. Compared with the national average, your *own* surgical rate of long-term impotence associated with nerve-sparing prostatectomy is:

lower about the same higher

6. In general, external conformal beam radiation has better long-term urinary incontinence outcomes than prostatectomy:

True False

7. In general, external conformal beam radiation has better long-term sexual function outcomes than prostatectomy:

True False

8. In your practice, all else being equal, married men with localized prostate cancer are more likely than unmarried men to have prostatectomy as opposed to a form of radiation

True False

9. There is an ongoing adjuvant trial for high risk prostate cancer for patients following radical prostatectomy (SWOG 9921). All receive 2 years of hormone therapy and 50% receive 6 cycles of chemotherapy.

* Are you aware of this trial? yes _____ no _____

* Would you be willing to enroll qualifying patients (5 - very likely; 1 - unlikely): 5 4 3 2 1

* Would decreasing reimbursement for GnRH analogs have any effect on your willingness to collaborate with medical oncologists in order to enter patients into this trial?

No effect _____ Some effect _____ Large effect _____

SECTION 3: Please provide the following information about yourself and your clinical practice:

1. Your age: _____

2. Your race/ethnicity: **White, non-Latino / African American / Latino / Asian or Pacific Islander / Other**

3. How many years have you been practicing urology? _____

4. Did you complete a fellowship in urologic oncology?

Yes

No

5. In your clinical practice, the percentage of white, non-Latino patients is:

<10%

10-30%

31-60%

>60%

6. In your clinical practice, the percentage of African American patients is:

<10%

10-30%

31-60%

>60%

7. In your clinical practice, the percentage of Latino patients is:

<10%

10-30%

31-60%

>60%

8. Please circle the average number of *prostatectomies* that you perform per year:

None

1-10

11-30

>30

9. Please circle the average number of *brachytherapy procedures* that you perform/assist per year:

None

1-10

11-30

>30

10. What percentage of the time do you refer your localized prostate cancer patients to a radiation oncologist for discussion of radiation as possible primary therapy?

<10%

10-25%

26-50%

51-75%

>75%

11. What percentage of the time do you refer your *high risk* localized prostate cancer patients to a medical oncologist for a second opinion and possible adjuvant therapy?

<10%

10-25%

26-50%

51-75%

>75%

12. Which best describes your clinical practice:

Academic

Private-practice

13. What is the bed size of the largest hospital in which you usually practice:

<100

101-300

>300

Thank you for your participation!
Please feel free to provide any comments in the space below

The Influence of Patient Race and Social Vulnerability on Urologist Treatment Recommendations in Localized Prostate Carcinoma

Thomas D. Denberg, MD, PhD,*†‡ Fernando J. Kim, MD,¶ Robert C. Flanigan, MD,§
Diane Fairclough, DrPH,†‡ Brenda L. Beaty, MSPH,§ John F. Steiner, MD, MPH,*‡
and Richard M. Hoffman, MD, MPH||

Background: In localized prostate carcinoma (PCa), many studies have found that black subjects receive radical prostatectomy (RP) less often than white subjects. Such disparities involve barriers to health care, comorbid illnesses, tumor characteristics, and patient preferences. It is unclear whether differences in urologist treatment recommendations also might play a role.

Methods: Using a randomized, 2×2 factorial design, we presented 2000 urologists with a clinical vignette and asked them to recommend treatment of a healthy 70-year-old patient with low-risk, clinically localized PCa. Options included either RP, external beam radiotherapy, brachytherapy, cryotherapy, observation, or hormonal therapy. There were 2 variables within 4 otherwise-identical versions of the vignette: 1) patient race (black vs. white) and 2) social vulnerability (middle-income and married vs. low-income and widowed). We used multivariable logistic regression to model the effects of patient race, social vulnerability, and their interaction on recommendations for RP versus radiotherapy.

Results: The response rate was 66.1% ($n = 1313$). Race and social vulnerability interacted ($P = 0.05$) such that the highly vulnerable black patient received an RP recommendation 14.4% less often than his less vulnerable counterpart; the difference between the 2 white patients was 4.2%.

Discussion: Race interacts with social vulnerability to influence urologist recommendations for RP. Because PCa tends to be more lethal in blacks, urologists may view such patients as good candidates for RP. However, black race may amplify perceptions of social vulnerability, heightening urologists' concerns about poor surgical outcomes and follow-up. These findings affirm the importance of modeling interactions between race/ethnicity and other social variables in health disparities research.

Key Words: health disparities, localized prostate carcinoma, treatment, social support, socioeconomic status

(*Med Care* 2006;44: 1137–1141)

Racial and ethnic disparities in cancer treatment have been widely documented.¹ For localized prostate carcinoma, numerous studies during the past decade have reported that black patients receive radical prostatectomy significantly less often than white patients.^{2–13} Several studies also have found that black patients receive less curative therapy overall (prostatectomy or radiation).^{3,4,11,13–15} Differences in treatment are likely to involve structural barriers to health care, comorbid illnesses and tumor characteristics, and patient treatment preferences.¹⁶ Differences in physician treatment recommendations also may be implicated, but this is poorly understood. Because physicians do not generally furnish researchers with information about treatment recommendations for actual patients, we surveyed a national sample of urologists to evaluate how a patient's race and other social characteristics as represented in a clinical vignette would influence their recommendations for radical prostatectomy and aggressive therapy in general.

Methods

We selected physicians who listed their specialty as Urology from the American Medical Association (AMA) Master List of Physicians, excluding trainees, pediatric urologists, and urologists uninvolved in patient care. We further limited our sampling to urologists who were linked by unique identifiers to the National Drug Council (NDC) database as prescribers of hormonal therapies (the All Antineoplastic Therapeutic class) to identify urologists directly involved in the treatment of prostate carcinoma. Out of a total of 6,104 urologists who met these criteria, we selected a random sample of 2000 to receive a mailed survey.

Following Dillman survey methodology,¹⁷ and modeled on a previous survey by Fowler et al,¹⁸ we mailed each urologist a pretested survey, \$10 cash incentive, and postage-paid return envelope. Nonrespondents received reminder letters and up to 2 additional mailings of the survey. We

From the *General Internal Medicine and †Comprehensive Cancer Center, and ‡Colorado Health Outcomes Program, University of Colorado Health Sciences Center, Denver; §Urology, Loyola University, Chicago, Illinois; ¶Urology, Denver Health Medical Center, University of Colorado Health Sciences Center, Denver; and ||General Internal Medicine, Veterans Affairs Hospital, University of New Mexico, Albuquerque.

Supported by the Department of Defense (DOD) Grant No. W81XWH-04-1-0897 (Denberg, PI).

Reprints: Dr. Thomas Denberg, 4200 E. 9th Ave., B-180, Division of General Internal Medicine, University of Colorado at Denver and Health Sciences Center, Denver, CO 80262. E-mail: tom.denberg@uchsc.edu.

Copyright © 2006 by Lippincott Williams & Wilkins

ISSN: 0025-7079/06/4412-1137

explained that the purpose of the confidential survey was to better understand national patterns of care for early-stage prostate cancer. We did not mention our interest in assessing the potential influence of patient race on treatment recommendations. If urologists indicated they were retired, we removed them from the denominator. If a noncompleted survey was returned as undeliverable, we substituted randomly another urologist who practiced in the same town or city.

The survey collected information about urologist demographic and clinical practice characteristics, including age, gender, years in practice, type of practice (academic vs. private), fellowship training in urologic oncology, annual procedure volume for radical prostatectomy and brachytherapy, and black and Latino composition of patients seen in practice. The size of the metropolitan area of each urological practice was derived from cross-referencing each urologist zip code to its U.S. Census Core-Based Statistical Area. The survey included a clinical vignette that asked urologists to make a treatment recommendation for a 70-year-old, generally healthy and active patient who had moderate-grade, low-risk (Gleason 3+3, PSA 3.2), clinically localized prostate carcinoma. The vignette specified that the patient's erectile function was satisfactory for intercourse, his urinary symptoms were mild (AUA symptom score of 6), and he had Medicare coverage and lived close to a major medical center. The patient was interested primarily in cure but, to the extent possible, he also wanted to avoid treatment that would interfere with his sexual function. We asked urologists to recommend a single form of treatment that could include radical prostatectomy, external beam radiotherapy, brachytherapy, cryotherapy, or observation ("watchful waiting"). Hormonal therapy could be selected in addition to, or instead of, these other options.

Using a 2×2 factorial design, we produced 4 versions of the vignette. The patient's medical characteristics, insurance status, geographic proximity to treatment, and preferences for cure and side effects were identical in each, but 2 elements varied dichotomously: 1) the patient's race (black vs. white, incorporating an appropriate photograph) and 2) his level of social vulnerability. Social vulnerability influences susceptibilities, responses, and outcomes of illness, and is influenced by traits such as age, physical and mental disability, family structure, social networks, income and material resources, and housing.¹⁹⁻²¹ The patient in the vignette was either "widowed, unemployed, and living in low-income housing" (high vulnerability) or else he was "a retired electrical engineer with a very concerned wife" (low vulnerability). At random, each urologist received one version of the vignette.

We used multivariable logistic regression to model the effects of patient race, social vulnerability, and the interaction between these 2 variables on recommendations for: 1) radical prostatectomy versus radiotherapy (external beam or brachytherapy), and 2) aggressive therapy (radical prostatectomy, radiotherapy, or cryotherapy) versus watchful waiting. We displayed our results in terms of bivariate associations between patient race, social vulnerability, and race-social vulnerability interactions, on the one hand, and urologist treatment recommendations, on the other. We also computed relative risks and risk differences between each of the 2

possible main effects (race and social vulnerability) and for both races stratified by social vulnerability. All statistical analyses were conducted by use of SAS (SAS Institute, Inc., Cary, NC). This study was approved by the Colorado Multiple Institutional Review Board (COMIRB).

Results

The response rate was 66.1% ($n = 1313$), excluding 15 urologists who returned a postcard indicating they were retired. There were no differences between respondents and nonrespondents in terms of all measures available for both groups, including age, gender, metropolitan size of practice location, region of the country, or number of prescriptions generated quarterly for hormonal therapy. Table 1 summarizes the demographic and clinical practice characteristics of the respondents. The sample was overwhelmingly white (83.3%), male (97.9%), and had been in practice for an average of 19.5 years. Approximately 7% had completed a fellowship in urologic oncology, and 93% were in private practice. Majorities practiced in a metropolitan area with a population of at least 50,000 and had fewer than 10% black or Latino patients in their practices. The distribution of Table 1 variables and response rates were similar for recipients of each version of the vignette.

For all vignette versions combined, 6.4% of urologists recommended watchful waiting and 93.5% recommended some form of aggressive therapy: radical prostatectomy (29.3%), radiotherapy (62.3%), or cryotherapy (1.8%). Of those recommending radiotherapy, and without difference based on vignette version, brachytherapy was the overwhelming choice (85.1%). Adjunctive hormonal therapy was recommended by 11.9% of urologists.

Table 2 summarizes the impact of race and socioeconomic vulnerability on urologist treatment recommendations. Social vulnerability influenced recommendations for radical prostatectomy over radiotherapy such that the less-vulnerable black and white patients combined received a radical prostatectomy recommendation 9.3% more often than their highly vulnerable counterparts ($P = 0.0005$). There also was a race-social vulnerability interaction ($P = 0.05$). The less-vulnerable black patient received a radical prostatectomy recommendation 14.4% more often than the highly vulnerable black patient, whereas the difference was 4.2% for the 2 white patients.

Social vulnerability also had a significant, albeit small, overall effect on recommendations for watchful waiting ($P = 0.004$, Table 3). The highly vulnerable black and white patients combined received a watchful waiting recommendation 4.2% more often than their less vulnerable counterparts. The highly vulnerable white patient received a watchful waiting recommendation 6.9% more often than the less vulnerable white patient while the difference was 1.3% between the 2 black patients. There was, however, no significant race-social vulnerability interaction in this model.

Discussion

In a clinical vignette, we found that a patient's social vulnerability strongly influenced urologists' treatment recommendations for localized prostate carcinoma. The more vul-

TABLE 1. Sociodemographic and Clinical Practice Characteristics of Survey Respondents

Category	Percent
Respondents	1313 (66.1%)
Male	97.9
Mean age, yr (SD)	52.8 (10.3)
Mean yrs in practice (SD)	19.5 (10.2)
Race/ethnicity	
White	83.3
Black	2.0
Latino	2.1
Asian/Pacific Islander	10.5
Other	2.1
Completed fellowship	7.2
Type of practice	
Academic	7.0
Private	93.0
Average prostatectomies/year	
None	10.9
1–10	33.2
11–30	41.7
>30	14.1
Average brachytherapies/year	
None	32.0
1–10	25.9
11–30	31.9
>30	9.0
Size of metropolitan area (CBSA)	
<10,000	1.7
10,000 to 49,999	10.3
50,000 to 2.5 million	57.8
≥2.5 million	30.3
Hospital bed size of primary practice	
<100 beds	7.8
101–300 beds	64.7
>300	27.5
Race of patient population	
<10% Black	52.4
10–30% Black	36.6
>30% Black	11.0
Ethnicity of patient population	
<10% Latino	71.9
10–30% Latino	22.7
>30% Latino	5.4

CBSA indicates core-based statistical area.

nerable patients experienced lower rates of recommendation for aggressive therapy as well as radical prostatectomy, specifically. Race also interacted with social vulnerability to influence the selection of radical prostatectomy for black patients, specifically. These results offer further evidence that interactions between race and other social variables, often overlooked in health disparities research, may be important across a large number of health conditions.^{22–25}

This is the first study to describe, using methodology that minimizes the influence of unmeasured confounders,

how urologist treatment recommendations for prostate cancer are influenced by a patient's race and socioeconomic circumstances. To the extent that a hypothetical scenario illuminates clinical decision-making in the real world, this study is noteworthy because it elucidates the influence of these variables individually and in combination. The results also show that nonclinical factors, such as social vulnerability, exert a strong influence on physician recommendations. This is important because physician recommendation is often the principal determinant of treatment that patients receive.²⁶

In the vignette, a highly vulnerable black patient received the lowest overall rate of recommendation for radical prostatectomy whereas his less socially vulnerable counterpart received the highest. The difference, quite large, was 14.4% and compares with a 4.2% difference between the 2 white patients whose degree of social vulnerability was described in identical terms. Because prostate cancer has higher rates of biochemical recurrence²⁷ and tends to be more lethal in black than white subjects,⁴ urologists may feel that married, middle-class black patients with moderate-grade, low-PSA tumors are good candidates for prostatectomy, which urologists regard as the most definitive option for cure.¹⁸ In comparison, urologists may reason that socioeconomically disadvantaged patients are less appropriate for surgery. Such patients might be more likely to experience postoperative complications and require longer hospital stays. Analgesia, diet, fluid intake, bowel habits, physical activity, and Foley catheter hygiene require careful attention in the postoperative period. Patients who are less educated and socially isolated may have significant difficulties with these details. Second, socially vulnerable patients may have poorer adherence to follow-up, including regular PSA surveillance. Ultimately, urologists may assume that patients who are socially disadvantaged *and* black are especially susceptible to poor outcomes and follow-up. In other words, black race may amplify their perceptions of social vulnerability and its adverse consequences. It is unclear whether such perceptions would be shaped by reality-based probabilities, or whether they would instead reflect implicit biases or stereotypes,²⁸ but both possibilities have some merit.²⁹

A previous study in cardiovascular disease found that patients' socioeconomic status strongly influenced physician perceptions of patient intelligence and likelihood of having social supports and adhering to medical advice.²⁹ Another study found that physicians perceive socioeconomically disadvantaged patients as having higher rates of medical non-adherence, adversely influencing their referrals for kidney transplantation.³⁰ In prostate cancer, if urologists assume that patients will do poorly with, or are unlikely to accept prostatectomy if offered, they may not mention it or may downplay its suitability in comparison with other options.

Study Limitations

We did not study the actual relationship between social vulnerability and receipt of medical care. In addition, we were unable to assess how individual urologists interpreted the vignettes. Instead, our goal was to evaluate whether the presentation of a small number of variables implicated in the

TABLE 2. Urologist Treatment Recommendations: RP Versus XRT (n = 1205)

Patient Variables	RP % (n)	XRT % (n)	Risk Difference* (%)	Relative Risk [†]	P [‡]
Black	31.6 (194)	68.4 (419)	0.0	1.00	0.74
White	31.6 (187)	68.4 (405)	(−0.1 to 0.1)	(0.85–1.18)	
High vulnerability	26.8 (155)	73.2 (424)	9.3	0.74	0.0005
Low vulnerability	36.1 (226)	63.9 (400)	(4.1–14.5)	(0.63–0.88)	
Black, high vulnerability	23.9 (68)	76.1 (216)	14.4	0.63	0.05
Black, low vulnerability	38.3 (126)	61.7 (203)	(7.1–21.6)	(0.49–0.80)	
White, high vulnerability	29.5 (87)	70.5 (208)	4.2	0.88	
White, low vulnerability	33.7 (100)	66.3 (197)	(−3.3 to 11.7)	(0.69–1.11)	

*Risk difference: second minus first group receiving a recommendation for RP vs. XRT.

[†]Relative risk: first versus second group receiving a recommendation for RP vs. XRT.

[‡]Wald χ^2 level of significance based on full logistic regression model of patient race, social vulnerability, and race; social vulnerability based on interaction on radical prostatectomy versus radiotherapy.

RP indicates radical prostatectomy; XRT, radiotherapy (brachytherapy or external beam).

TABLE 3. Urologist Treatment Recommendations: Aggressive vs. WW* (n = 1313)

Patient Variables	Aggressive % (n)	WW % (n)	Risk Difference [†] (%)	Relative Risk [‡]	P [§]
Black	94.5 (623)	5.5 (36)	−1.9	1.02	0.41
White	92.7 (606)	7.3 (48)	(−4.5 to 0.1)	(1.00–1.05)	
High vulnerability	91.5 (590)	8.5 (55)	4.2	0.96	0.004
Low vulnerability	95.7 (639)	4.3 (29)	(1.5–6.8)	(0.93–0.98)	
Black, high vulnerability	93.8 (289)	6.2 (19)	1.3	0.99	0.10
Black, low vulnerability	95.2 (334)	4.8 (17)	(−3.3 to 11.7)	(0.95–1.02)	
White, high vulnerability	89.3 (301)	10.7 (36)	6.9	0.93	
White, low vulnerability	96.2 (305)	3.8 (12)	(3.0–10.8)	(0.89–0.97)	

*Aggressive therapy indicates radical prostatectomy, radiotherapy, or cryotherapy.

[†]Risk difference: second minus first group receiving a recommendation for curative therapy vs. WW.

[‡]Relative risk: first versus second group receiving a recommendation for curative therapy vs. WW.

[§]Wald χ^2 level of significance based on full logistic regression model of patient race, social vulnerability, and race. Social vulnerability interaction based on on curative therapy versus watchful waiting.

WW indicates watchful waiting.

broader concept of social vulnerability^{19–21} influenced treatment recommendation patterns among a nationally-representative sample of urologists. We recognize that our results may not be generalizable to actual patients. In addition, they would not be applicable to many patients whose clinical characteristics differ from those in the vignette. For example, if the patient we presented had been much younger or had had higher risk disease, this would likely have attenuated the differences we found in rates of recommendation for prostatectomy. It is possible that physical features of the photographed models (eg, facial expression, hairstyle, hand gestures), rather than skin color alone, influenced urologists' recommendations.³¹ Even if this were the case, however, it is nonetheless important that a patient's superficial characteristics would have had such an effect. There was also some potential for nonresponse bias. Finally, our results only indirectly support the idea that clinicians view black patients as more socially vulnerable than white patients. Despite these limitations, we believe the vignette offers a compelling illustration of how the race/ethnicity of patients might influence physician perceptions of social vulnerability to affect treatment recommendations. These, in turn, could help to explain overall differences in treatment actually received. Our findings are bolstered by a balanced, randomized design, a large,

nationally-representative sample of urologists who treat prostate carcinoma, and by the ability to study the effects of patient race and social vulnerability in the absence of common, unmeasured confounders.

Conclusion

Our results reaffirm the importance in health disparities research of modeling interactions between race/ethnicity and multiple variables that reflect diverse aspects of a patient's socioeconomic circumstances.

ACKNOWLEDGMENTS

Trisha V. Melhado, BS, assisted with the survey mailing and data entry.

REFERENCES

- Shavers VL, Brown ML. Racial and ethnic disparities in the receipt of cancer treatment. *J Natl Cancer Inst.* 2002;94:334–357.
- Denberg TD, Beaty BL, Kim FJ, et al. Marriage and ethnicity predict treatment in localized prostate carcinoma. *Cancer.* 2005;103:1819–1825.
- Desch CE, Penberthy L, Newschaffer CJ, et al. Factors that determine the treatment for local and regional prostate cancer. *Med Care.* 1996; 34:152–162.
- Fowler JE Jr, Bigler SA, Bowman G, et al. Race and cause specific survival with prostate cancer: influence of clinical stage, Gleason score, age and treatment. *J Urol.* 2000;163:137–142.

5. Harlan L, Brawley O, Pommerenke F, et al. Geographic, age, and racial variation in the treatment of local/regional carcinoma of the prostate. *J Clin Oncol*. 1995;13:93–100.
6. Hoffman RM, Harlan LC, Klabunde CN, et al. Racial differences in initial treatment for clinically localized prostate cancer. Results from the prostate cancer outcomes study. *J Gen Intern Med*. 2003;18:845–853.
7. Jones GW, Mettlin C, Murphy GP, et al. Patterns of care for carcinoma of the prostate gland: results of a national survey of 1984 and 1990. *J Am Coll Surg*. 1995;180:545–554.
8. Klabunde CN, Potosky AL, Harlan LC, et al. Trends and black/white differences in treatment for nonmetastatic prostate cancer. *Med Care*. 1998;36:1337–1348.
9. Mettlin CJ, Murphy GP, Cunningham MP, et al. The National Cancer Data Base report on race, age, and region variations in prostate cancer treatment. *Cancer*. 1997;80:1261–1266.
10. Morris CR, Snipes KP, Schlag R, et al. Sociodemographic factors associated with prostatectomy utilization and concordance with the physician data query for prostate cancer (United States). *Cancer Causes Control*. 1999;10:503–511.
11. Schapira MM, McAuliffe TL, Nattinger AB. Treatment of localized prostate cancer in African-American compared with Caucasian men. Less use of aggressive therapy for comparable disease. *Med Care*. 1995;33:1079–1088.
12. Shaw M, Elterman L, Rubenstein M, et al. Changes in radical prostatectomy and radiation therapy rates for African Americans and whites. *J Natl Med Assoc*. 2000;92:281–284.
13. Underwood W, De Monner S, Ubel P, et al. Racial/ethnic disparities in the treatment of localized/regional prostate cancer. *J Urol*. 2004;171:1504–1507.
14. Gilliland FD, Hunt WC, Key CR. Ethnic variation in prostate cancer survival in New Mexico. *Cancer Epidemiol Biomarkers Prev*. 1996;5:247–251.
15. Harlan LC, Potosky A, Gilliland FD, et al. Factors associated with initial therapy for clinically localized prostate cancer: prostate cancer outcomes study. *J Natl Cancer Inst*. 2001;93:1864–1871.
16. Fiscella K, Franks P, Gold MR, et al. Inequality in quality: addressing socioeconomic, racial, and ethnic disparities in health care. *JAMA*. 2000;283:2579–2584.
17. Dillman DA. *Mail and Internet Surveys: The Tailored Design Method*. 2nd ed. New York: John Wiley Co.; 2000.
18. Fowler FJ Jr, McNaughton Collins M, Albertsen PC, et al. Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer. *JAMA*. 2000;283:3217–3222.
19. Cutter SL, Boruff BJ, Shirley WL. Social Vulnerability to Environmental Hazards. *Social Sci Q*. 2003;84:242–261.
20. Putnam RD. *Bowling Alone: Collapse and Revival of the American Community*. New York: Simon & Schuster; 2000.
21. Dwyer A, Zoppous C, Nielsen O, et al. Quantifying social vulnerability: a methodology for identifying those at risk to natural hazards. *Geoscience Australia Record*. 2004;14.
22. Farmer MM, Ferraro KF. Are racial disparities in health conditional on socioeconomic status? *Soc Sci Med*. 2005;60:191–204.
23. Yost K, Perkins C, Cohen R, et al. Socioeconomic status and breast cancer incidence in California for different race/ethnic groups. *Cancer Causes Control*. 2001;12:703–711.
24. Bae SC, Hashimoto H, Karlson EW, et al. Variable effects of social support by race, economic status, and disease activity in systemic lupus erythematosus. *J Rheumatol*. 2001;28:1245–1251.
25. Nicolaidis C, Ko CW, Saha S, et al. Racial discrepancies in the association between paternal vs. maternal educational level and risk of low birthweight in Washington State. *BMC Pregnancy Childbirth*. 2004;4:10.
26. Demark-Wahnefried W, Schildkraut JM, Iselin CE, et al. Treatment options, selection, and satisfaction among African American and white men with prostate carcinoma in North Carolina. *Cancer*. 1998;83:320–330.
27. Tarman GJ, Kane CJ, Moul JW, et al. Impact of socioeconomic status and race on clinical parameters of patients undergoing radical prostatectomy in an equal access health care system. *Urology*. 2000;56:1016–1020.
28. Baron AS, Banaji MR. The development of implicit attitudes. Evidence of race evaluations from ages 6 and 10 and adulthood. *Psychol Sci*. 2006;17:53–58.
29. van Ryn M, Burke J. The effect of patient race and socio-economic status on physicians' perceptions of patients. *Soc Sci Med*. 2000;50:813–828.
30. Powe NR, Boulware LE. The uneven distribution of kidney transplants: getting at the root causes and improving care. *Am J Kidney Dis*. 2002;40:861–863.
31. Blair IV. The malleability of automatic stereotypes and prejudice. *Pers Soc Psychol Rev*. 2002;6:242–261.

signing the diagnosis codes that appear in the physician/supplier claims and the recognition that there may be data quality issues with the codes. The codes that appear in the physician/supplier claims may not be clinician-assigned, a code must be submitted in order for the claim to be reimbursed by Medicare, and the code may represent a suspected but not clinically confirmed condition. Requiring the condition to appear in both the hospital and physician claims or the presence of the code twice in the physician claims increases the likelihood that the claims are identifying true comorbid conditions.

We did not explore varying time frames for measuring comorbid conditions using Medicare claims in this study, because it was beyond the scope of what we could accomplish in a single article. Our sensitivity analysis was limited to a comparison of condition prevalences with and without the rule-out algorithm applied, an assessment that had not been documented previously. At least one other group has examined different lookback periods for optimal comorbidity measurement with Medicare claims.³ This group recommended using 2 years of inpatient data and 1 year of outpatient and auxiliary claims as one possible strategy. Dr. Fleming has identified the need for additional analyses to further assess different lookback periods and methods for identifying comorbid conditions from claims data. We encourage him as well as other interested investigators to pursue such analyses, as they would further enhance the utility of claims data in health services, epidemiologic, and outcomes research studies.

Carrie N. Klabunde, PhD
Linda C. Harlan, PhD
Joan L. Warren, PhD
 National Cancer Institute
 Rockville, Maryland

REFERENCES

1. Klabunde CN, Harlan LC, Warren JL. Data sources for measuring comorbidity: a comparison of hospital records and Medicare claims for cancer patients. *Med Care*. 2006; 44:921–928.
2. Klabunde CN, Potosky AL, Legler JM, et al. Development of a comorbidity index using physician claims data. *J Clin Epidemiol*. 2000; 53:1258–1267.
3. Zhang JX, Iwashyna TJ, Christakis NA. The performance of different lookback periods and sources of information for Charlson comorbidity adjustment in Medicare claims. *Med Care*. 1999;37:1128–1139.

Vulnerability—More Than a Construct, A Clinical Reality: Response to Denberg et al, December 2006 *Medical Care*

To the Editor:

The recent article by Denberg and colleagues, titled “The Influence of Patient Race and Social Vulnerability on Urologist Treatment Recommendations in Localized Prostate Carcinoma” makes an important contribution to the literature by focusing on the interactivity of patient demographics in clinical decision-making.¹ Researchers have long studied the effects of race/ethnicity and income on health care access, quality, and health outcomes. Rarely, however, do we (as Denberg and colleagues have done) explicitly recognize the concomitant and potentially combinatorial effects of these risk factors.

The concept of vulnerability has been well defined, but primarily in categorical ways. For example, vulnerable populations include the poor, the elderly, the uninsured, the homeless, and many other demographic divisions.² But more recent work encourages us to think broadly about vulnerability by recognizing that risk factors frequently overlap (eg, the poor are more likely to also be uninsured). Shi and Stevens are only among the latest to argue that we begin to view vulnerable populations by the collection of health or health care risk factors they possess and work harder to understand their interactivity.³

Previous studies have counted the number of risk factors a person has and have shown clear gradients in health services use, quality of care, and health status.^{4–8} But at its simplest and arguably finest, the vulnerability construct can be simply measured, as Denberg and colleagues have done, by examining those who have both risk factors versus one or none (black race/ethnicity and low income/widowed). Conveyed as an interaction term, the interpretation is complex, but the message is quite clear: in clinical practice, as elsewhere, vulnerability is considerably more than the sum of its parts.

Gregory D. Stevens, PhD

University of Southern California Keck
 School of Medicine

REFERENCES

1. Denberg TD, Kim FJ, Flanigan RC, et al. The influence of patient race and social vulnerability on urologist treatment recommendations in localized prostate carcinoma. *Med Care*. 2006; 44:1137–1141.
2. Aday L. *At Risk in America: The Health and Health Care Needs of Vulnerable Populations in the United States*. 2nd ed. San Francisco, CA: Jossey-Bass; 2001.
3. Shi L, Stevens GD. *Vulnerable Populations in the United States*. San Francisco, CA: Jossey-Bass; 2005.
4. Stevens GD, Seid M, Mistry R, et al. Disparities in primary care for vulnerable children: the influence of multiple risk factors. *Health Serv Res*. 2006;41:507–531.
5. Stevens GD. Gradients in the health status and developmental risks of young children: the combined influences of multiple social risk factors. *Matern Child Health J*. 2006;10:187–199.
6. Shi L, Stevens GD. Vulnerability and unmet health care needs. The influence of multiple risk factors. *J Gen Intern Med*. 2005;20:148–154.
7. Shi L, Stevens GD. Vulnerability and the receipt of recommended preventive services: the influence of multiple risk factors. *Med Care*. 2005;43:193–198.
8. Bauman LJ, Silver EJ, Stein RE. Cumulative social disadvantage and child health. *Pediatrics*. 2006;117:1321–1328.

Response to Letter From Dr. Gregory D. Stevens

To the Editor:

We agree with Dr. Stevens that more accurate and complex assessments of vulnerability will yield a better understanding of the causes of health disparities and more workable ideas about how to ameliorate them.^{1,2} Such associations can be measured either as an index of multiple aspects of vulnerability (numbers of risk factors), or as interactions among a smaller number of social variables. Further, the relationship between these measures can be assessed in relation either to patient-centered outcomes such as utilization of health services, quality of care, or health status, or in terms of their influence on clinician behavior. In our own study, for example, we found that urologists do not invariably recommend less often to a black patient a form of treatment they regard as superior simply because the patient is black. Instead, the interaction between race and other social variables suggests

that the meaning of race is conditioned on the perceived social context. Following the lead of social geographers^{3,4} and health researchers like Dr. Stevens, we encourage the continued development of novel methodologies that will improve our ability to measure, quantify, and recognize the enormous range of factors implicated in the concept of social vulnerability.

Thomas D. Denberg, MD, PhD
John F. Steiner, MD, MPH
 University of Colorado at Denver and
 Health Sciences Center

REFERENCES

1. Barbeau EM, Krieger N, Soobader MJ. Working class matters: socioeconomic disadvantage, race/ethnicity, gender, and smoking in NHIS 2000. *Am J Public Health*. 2004;94: 269–28.
2. Krieger N. Refiguring “race”: epidemiology, racialized biology, and biological expressions of race relations. *Int J Health Serv*. 2000;30: 211–21.
3. Cutter S, Boruff B, Shirley W. Social vulnerability to environmental hazards. *Soc Sci Q*. 2003; 84:242–261.
4. Dwyer A, Zoppous C, Nielsen O, et al. Quantifying social vulnerability: a methodology for identifying those at risk for natural hazards. *Geoscience Australia Record*. 2004/14.

ERRATUM

Lorig KR, Ritter PL, Laurent DD, et al. Internet-based Chronic Disease Self-Management: a Randomized Trial. *Med Care*. 2006;44:964–971.

In the article cited above, 2 of the effect sizes (differences in change scores in intervention vs. usual care groups, divided by pooled baseline standard deviation) in Table 2 on page 967 were incorrect. The effect sizes were reported as 0.032 for pain and 0.229 for shortness of breath. The effect sizes should have been 0.106 for pain and 0.097 for shortness of breath. The error did not affect our findings or conclusion and the sentence that effect sizes were modest remains unchanged. The authors offer their sincere apologies to any readers who may have been misled.

Self-reported volume of radical prostatectomies among urologists in the USA

Thomas D. Denberg^{1,2,3}, Robert C. Flanigan⁵, Fernando J. Kim⁴, Richard M. Hoffman⁶ and John F. Steiner^{1,3}

¹General Internal Medicine, ²Comprehensive Cancer Center, ³Colorado Health Outcomes Program, ⁴Urology, Denver Health Medical Center, University of Colorado Health Sciences Center, Denver, CO, ⁵Urology, Loyola University, Maywood, IL, and ⁶General Internal Medicine, Veterans Affairs Hospital, University of New Mexico, Albuquerque, NM, USA

Accepted for publication 12 October 2006

OBJECTIVE

To evaluate the variability in the volume of radical retropubic prostatectomy (RP) performed by urologists in the USA, and the physician characteristics that predict RP volume, as previous studies showed that individual surgeon volume for RP is associated with clinical outcomes.

METHODS

In a nationwide, representative survey of 2000 urologists who treat prostate carcinoma in the USA, we asked respondents to indicate a numerical range of RPs they perform each year (none, 1–10, 11–30, and >30, the last which we defined as 'high volume'). We then identified characteristics of the provider and practice associated with a high volume of RPs.

Supplementing survey results with other national data, we estimated the proportion of all RPs in the USA performed by 'high-volume' urologists.

RESULTS

The survey response rate was 66.1% (1313 urologists) with no differences between the respondents and non-respondents for the measured demographic variables. Among urologists who performed RPs (89.1% of the sample), 37.3% did ≤10, 46.9% 11–30 and 15.8% >30 RPs/year. Academic and urological oncology fellowship-trained urologists were, respectively, 41% and 27% more likely than private-practice and non-fellowship-trained urologists to have a high volume of RPs. Of all RPs performed yearly in the USA, only an

estimated 46.1% were by high-volume urologists.

CONCLUSION

A significant proportion of urologists report a RP volume that might be associated with higher rates of cardiac, respiratory, vascular, wound-healing, and genitourinary complications. Further study is needed to characterize the possible relationships between RP volume and tumour recurrence, survival, and long-term erectile dysfunction and incontinence.

KEYWORDS

surgery, prostatectomy, surgical volume, postoperative complications

INTRODUCTION

Better surgical outcomes have been linked to greater surgeon and hospital volume for many procedures, including radical retropubic prostatectomy (RP) [1–8]. Surgeons who perform more RPs have been found to have, on average, lower rates of cardiopulmonary, vascular, wound-healing and urinary complications [5,8] and, possibly, fewer positive surgical margins [3]. However, no minimum volume thresholds have been rigorously established for any RP outcomes. Little is known about the variability in RP volume among urologists in the USA, and about the characteristics of urologists that can be used to predict RP volume. We carried out a nationwide representative survey of urologists who treat prostate carcinoma, to identify characteristics of the provider and practice associated with high self-reported

RP volume. Supplementing survey results with other national data, we also estimated the proportion of all RPs in the USA performed by urologists who reported high RP volumes.

METHODS

We selected physicians who listed their speciality as 'urology' from the American Medical Association (AMA) Master List of Physicians, excluding trainees, paediatric urologists, and urologists not involved in patient care. We further limited our sampling to urologists who were linked by unique identifiers to the National Drug Council database as prescribers of hormonal therapies, to identify urologists directly involved in treating prostate carcinoma. Of 6104 urologists who met these criteria, we

selected a random sample of 2000 to receive a mailed survey. The survey was administered between February and May 2005 and was approved by the Colorado Multiple Institutional Review Board.

Following Dillman survey methods [9], we mailed each urologist a pre-tested survey, a US\$ 10 cash incentive, and postage-paid return envelope. Non-respondents received reminder letters and up to two additional mailings of the survey. We explained that the purpose of the confidential survey was to better understand the national patterns of care for early-stage prostate cancer. If urologists indicated that they were retired, we removed them from the denominator. If an uncompleted survey was returned as undeliverable, we substituted at random another urologist who practised in the same town or city.

The survey collected information about the demographic and clinical practice characteristics of the urologists. The size of the metropolitan area of each urological practice was derived from cross-referencing each urologist's Zip code to its USA Census Core Based Statistical Area (CBSA). We also asked urologists to specify their yearly RP and brachytherapy volume. To ensure that results were statistically sound and clinically meaningful, and because providers are more likely to recall a range rather than an exact number of procedures, we assessed provider volume as a categorical rather than a continuous variable. Response categories, based on a range of values gleaned from previous studies of RP volume [5,8] and identical to those used by Nuttall *et al.* [10] included none, 1–10, 11–30 and >30 RPs/year. We defined >30 RPs/year as high volume. By necessity, this was subjective, because no minimal RP thresholds have been properly established. Nonetheless, at least 31 RPs/year falls between a threshold of 16 associated with better outcomes as specified by Begg *et al.* [8] and 40 RPs/year specified by Hu *et al.* [5].

We determined significant associations ($P < 0.05$ using chi-square test for categorical variables) between individual urologist characteristics and three categories of RP volume for urologists who performed RP. We used multivariate stepwise logistic regression to identify significant predictors of performing 1–30 RPs/year, vs >30 RPs/year. We determined *a priori* that the independent variables in the logistic model would be those significantly associated with RP volume in bivariate analyses based on a P value of ≤ 0.25 . Results of the logistic regression model are shown as risk ratios associated with each independent variable adjusted for the others. Risk ratios were computed as corrections of the adjusted odds ratios [11].

Using national data and survey results, we estimated the total number and proportion of urologists in the USA whose yearly RP volume was >30/year. First, using weighted frequencies of ICD-9-CM procedure code 60.5 (radical RP) in the National Hospital Discharge Survey dataset [12], the total number of RPs in the USA in 2004 was 54 711. (While the Surveillance, Epidemiology and End Results study can also be used to determine procedure rates, these data were unavailable for 2004.) We then estimated the number of urologists who perform RP as the proportion

who performed RP in our nationally representative survey multiplied by the total number of urologists in the USA who treat prostate carcinoma, identified through the comprehensive AMA physician file. We determined the upper and lower limits for the number of RPs performed by high-volume urologists as follows. For the upper limit, we assumed that urologists in the lower-volume categories performed the minimum number of procedures possible. Thus, we subtracted from the total number of RPs for the year 2004 the sum of: (i) the proportion of urologists who perform 1–10 RPs/year multiplied by the total number of urologists who perform RP multiplied by 1 RP/year; and (ii) the proportion of urologists who perform 11–30 RPs/year multiplied by the total number of urologists who perform RP multiplied by 11 RPs/year. We used an analogous approach to determine the lower limit by assuming that urologists in the >30 RP/year category performed the minimum possible number of procedures, calculated as the proportion of urologists in this category multiplied by the total number of urologists who perform RP multiplied by 31 RPs/year. The mean of the upper and lower limits served as our point estimate for the total number of RPs performed by high-volume urologists, then used to calculate the overall proportion of all RPs performed by urologists in this group. As a sensitivity analysis, we re-calculated the upper and lower limits by varying the number of urologists who perform RP by ± 500 and by varying the proportion who perform more and less than 30 RPs by $\pm 5\%$.

RESULTS

The response rate was 66.1% (1313 urologists), excluding 15 who returned a postcard indicating that they were retired. There were no differences between respondents and non-respondents in terms of age, gender, metropolitan size of practice location, region of the country, or the number of prescriptions generated quarterly for hormonal therapy. The proportion of respondents who performed at least one RP per year was 89.1% (1170).

Table 1 summarizes the demographic and clinical practice characteristics of these respondents. The sample was overwhelmingly White, male, and had been in practice for a mean of 25.1 years; <10% were in academic

settings or had completed a urological oncology fellowship. A substantial majority practised in metropolitan areas with a population of $\geq 50\,000$. Of respondents, 37.3% performed ≤ 10 RPs/year (i.e. less than an average of one per month), 84.2% did ≤ 30 RPs/year (i.e. less than 2.5 per month) and 15.8% did >30 RPs/year.

Table 2 shows the significant predictors of RP volume. Urologists who worked in academic settings, were fellowship-trained in urological oncology, practised in hospitals with >300 beds and in metropolitan areas with $\geq 50\,000$ residents, or were earlier in their careers, performed significantly more RPs than their counterparts who worked in private practice, were not fellowship trained in urological oncology, practised in smaller hospitals and metropolitan areas, or were later in their careers. Table 3 shows the adjusted relative risks of performing >30 vs <30 RPs/year. Academic and urological oncology fellowship-trained urologists were, respectively, 41% and 27% more likely than private-practice and non-fellowship-trained urologists to do >30 RPs/year.

Finally, an estimated mean of 46.1 ($\pm 12.5\%$ in sensitivity analysis) of all RPs in the USA are done by urologists whose volume is >30 RPs/year. The results of a sensitivity analysis (Fig. 1) show little variation in these results on the basis of varying by ± 500 the number of urologists and by $\pm 5\%$ the proportion of urologists in each volume category.

DISCUSSION

Among urologists who perform RP, 37.3% reported doing ≤ 10 /year, while 84.2% reported ≤ 30 /year. Based on these and other national data, we estimated that fewer than half (46.1%) of all RPs in the USA are performed by high-volume urologists (i.e. those whose volume is >30 RPs/year). Academic practice and urological oncology fellowship training were the most important predictors of performing >30 RPs/year.

The present findings are important because RP is a technically complex operation in which lower hospital and surgeon volumes have each been associated with a variety of adverse outcomes, and because a significant proportion of urologists in the USA have RP volumes that fall within a 'lower' range, based on previous studies. For example, a recent study that adjusted for both clustering

Variable	Value, mean (SD) or %	TABLE 1 <i>The sociodemographic and clinical practice characteristics of 1170 survey respondents who perform RP</i>
Male	98.0	
Age, years	51.5 (10.0)	
Years in practice	25.1 (10.5)	
Race/ethnicity		
Caucasian	81.9	
African-American	1.8	
Latino	2.0	
Asian/Pacific Islander	9.9	
Other/Unknown	4.3	
Type of practice		
Academic	7.0	
Private	93.0	
Urological oncology fellowship	7.3	
Average no. RPs/year		
1–10	37.3	
11–30	46.8	
>30	15.9	
Average no. brachytherapy/year		
none	29.7	
1–10	26.9	
11–30	33.7	
>30	9.3	
Size of metropolitan area (CBSA)		
<50 000	11.4	
50 000–2.5 million	58.2	
≥ 2.5 million	30.4	
Hospital-beds in primary practice		
<100	7.4	
101–300	65.3	
>300	27.3	
Race of patient population		
<10% African-American	52.6	
10–30% African-American	36.5	
>30% African-American	10.0	
Ethnicity of patient population		
<10% Latino	71.0	
10–30% Latino	23.6	
>30% Latino	4.4	

and case mix found that the rates of cardiovascular, pulmonary, wound-healing, and urinary complications were significantly higher among urologists doing <16 RPs/year [8]. Another study incorporating case-mix adjustment found that urologists who did <40 RPs/year in a Medicare population had significantly higher rates of cardiac, respiratory, vascular, wound-healing, and genitourinary complications than those doing ≥40 RPs/year [5]. Notably, if the authors of the second study had estimated total urologist RP volumes assuming that 42% of all RPs are on patients aged ≥65 years [13], then their threshold would be closer to 95 RPs/year, a volume that applied to only 7.8% of urologists in their study.

Although a strong volume-outcome relationship has been shown for peri-operative complications, the relationship between surgeon volume and other important outcomes of RP has been less thoroughly assessed. Mortality rates are higher among patients of low-volume surgeons for a variety of complex surgical procedures, regardless of the volume of the hospitals in which they practice [2]. However, RP is generally a low-mortality procedure with no evident relationship between surgeon volume and mortality [6]. Meanwhile, although a case-mix adjusted study of 44 university-based urologists found that lower RP volume was associated with a higher rate of positive surgical margins [3], no well-designed,

population-based studies have evaluated the impact of surgical volume on recurrence or duration of survival. Similarly, little is known about long-term erectile dysfunction and incontinence outcomes. These last two are of particular concern to patients because they are very common and can have profound effects on quality of life [14]. These outcomes could, at least in part, be associated with volume, as nerve-sparing RP is a particularly complicated procedure that is highly sensitive to surgical technique that, in turn, is likely to be influenced by surgeon experience [15].

There are some caveats. First, minimal volume thresholds have not been established for any RP outcomes. In previous RP-volume studies, it is unclear how volume categories were derived or whether they were defined before or after analysing the data. Not establishing thresholds beforehand increases the chance of showing a volume-outcome relationship that in reality does not exist [7]. While a recent survey of 212 urologists in the UK showed that 43% would set a minimum volume threshold at ≥10 cases/year for RP, this threshold was entirely subjective and probably influenced by the number of procedures that these urologists actually perform [10].

While a volume threshold *might* be necessary for ensuring favourable RP outcomes, it is unclear whether total experience or yearly volume would be more important. In either case, volume alone is unlikely to be sufficient to determine outcomes. At least two studies have shown that outcomes of RP vary significantly and are sensitive to small differences in performance even among high-volume providers [1,3].

The present study had several limitations. Most importantly, although the present results were consistent with 1998 survey data in which urologists performed a mean of 18 RPs/year [16], RP volume in both cases was self-reported and therefore subject to bias. However, urologists are much more likely to *overestimate* rather than underestimate their RP volume. There is a widespread perception both among professionals and the public that volume is a surrogate for procedural skill and high-quality outcomes. Just as physicians commonly overestimate their level of adherence to clinical practice guidelines [17], urologists might be subject to a social desirability bias when reporting their yearly

number of procedures. Stronger evidence in favour of overestimating RP volume comes from the most detailed, objective description of RP volume, published by Begg *et al.* [8], in which the estimated proportion of urologists who performed <10 RPs/year was actually more than twice what was found in the present survey. Also, despite the absence of significant differences between respondents and non-respondents in measured variables, response bias was possible. For example, urologists who perform few RPs might have been less likely than others to respond to the survey. However, ultimately any overestimation or skewing towards greater RP volume in the present study would only strengthen a potential concern that a large proportion of urologists perform too few procedures to minimize peri-operative complications.

For assessing surgeon volume, Medicare claims are often used. However, while this approach is useful for assessing relationships between provider volume and outcomes, aggregating patient claims to the provider level does not yield a nationally representative picture of variation in procedure volume among individual surgeons. In addition, the Centers for Medicare & Medicaid Services data do not include men aged <65 years and provider identifiers are absent in >10% of cases [18,19]. While our volume categories were based on previous work, it would have been desirable to include a category reflecting >100 RPs/year, as this is a threshold considered by many of the best surgeons to be a minimum standard for assuring the best results [20]. Finally, individual procedure volume varies by year and we did not assess cumulative experience, which might be a more important predictor of outcomes than yearly volume. Nonetheless, the ability to maintain surgical skill over time, even among very experienced surgeons, is likely to depend on performing a minimum number of procedures annually. We think therefore that a 1-year 'snapshot' of self-reported volume is meaningful.

Despite limitations, this work has significant strengths. The survey represents the largest and most recent nationally representative assessment of urologists in the USA. Unlike previous studies, it collected detailed information about the characteristics of individual urologists and related these to measures of RP volume. Finally, a response rate of 66.1% is excellent.

Variable	Volume (RPs/year)			P*
	1–10	11–30	>30	
Practice type				
Private	38.7	47.4	13.8	<0.001
Academic	13.7	39.7	46.6	
Urological oncology fellowship				
No	38.2	47.7	14.1	<0.001
Yes	26.0	32.5	41.6	
Hospital beds				
<300	41.0	45.8	13.3	<0.001
≥300	27.3	48.8	23.9	
Years in practice				
0–9	35.1	49.2	15.7	<0.001
10–19	29.3	50.9	19.8	
20–29	40.4	43.1	16.6	
≥30	48.9	41.8	9.3	
Metropolitan area size, no. residents				
<50 000	41.7	50.0	8.3	0.045
≥50 000	36.7	46.2	17.2	

TABLE 2
Bivariate predictors of RP volume (1170 in sample)

*Chi-square test for categorical variables.

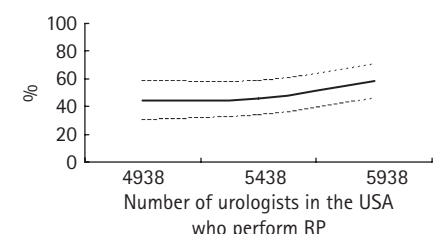
Variable/model	Overall relative risk (95% CI)
N	1170
Academic vs private practice	1.41 (1.18–1.80)
Fellowship vs no Fellowship	1.27 (1.10–1.58)
Years in practice	
0–9 (Reference)	
10–19	1.09 (1.01–1.14)
20–29	1.04 (0.96–1.10)
≥30	0.97 (0.88–1.03)

TABLE 3
Summary of logistic regression predicting >30 RPs/year among urologists in the USA who perform RP

Variables shown are those that retained significance in stepwise logistic regression; original predictor variables included practice type, fellowship training in urological oncology, years in practice, hospital-bed size, and metropolitan population of >50 000.

In conclusion, a large minority of urologists (37.3%) report performing ≤10 RPs/year, while a majority (84.2%) report <30 RPs/year. In addition, more than half of all RPs in the USA are done by urologists whose volume is <30 RPs/year. Although these results are based on self-report, they raise concerns that many surgeons might be performing too few RPs to reduce the adverse outcomes associated with RP. The present findings should stimulate further study based on more objective measures of volume. For example, in an effort to achieve the best possible outcomes, are minimal cumulative and yearly numbers of RPs required to attain and maintain technical proficiency, does fellowship

FIG. 1. Percentage of all RPs performed by urologists whose RP volume is >30/year. The solid line represents the point estimate for the proportion of all RPs performed in 2004 by high-volume urologists (i.e. >30 RPs/year); the dashed lines represent the upper and lower limits as determined by the extreme values obtained in a sensitivity analysis (see Methods section).



training in urological oncology hold advantages over residency training in high-volume centres, and should RP be regionalized through surgical centres of excellence? Especially important are studies that explore the relationship between RP volume, on the one hand, and survival and long-term incontinence and erectile dysfunction, on the other. Because only observational studies are feasible, these should assess RP volume through medical-record review or claims analyses, and should link these with patient-reported quality of life outcomes.

CONFLICT OF INTEREST

None declared. Source of funding: grant support from Department of Defense (DOD): W81XWH-04-1-0897 (Denberg, PI)

REFERENCES

- 1 Bianco FJ Jr, Riedel ER, Begg CB, Kattan MW, Scardino PT. Variations among high volume surgeons in the rate of complications after radical prostatectomy: further evidence that technique matters. *J Urol* 2005; **173**: 2099–103
- 2 Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003; **349**: 2117–27
- 3 Eastham JA, Kattan MW, Riedel E *et al.* Variations among individual surgeons in the rate of positive surgical margins in radical prostatectomy specimens. *J Urol* 2003; **170**: 2292–5
- 4 Ellison LM, Trock BJ, Poe NR, Partin AW. The effect of hospital volume on cancer control after radical prostatectomy. *J Urol* 2005; **173**: 2094–8
- 5 Hu JC, Gold KF, Pashos CL, Mehta SS, Litwin MS. Role of surgeon volume in radical prostatectomy outcomes. *J Clin Oncol* 2003; **21**: 401–5
- 6 Joudi FN, Konety BR. The impact of provider volume on outcomes from urological cancer therapy. *J Urol* 2005; **174**: 432–8
- 7 Nuttall M, van der Meulen J, Phillips N *et al.* A systematic review and critique of the literature relating hospital or surgeon volume to health outcomes for 3 urological cancer procedures. *J Urol* 2004; **172**: 2145–52
- 8 Begg CB, Riedel ER, Bach PB *et al.* Variations in morbidity after radical prostatectomy. *N Engl J Med* 2002; **346**: 1138–44
- 9 Dillman DA. *Mail and Internet Surveys: the Tailored Design Method*, 2nd edn. New York: John Wiley Co., 2000
- 10 Nuttall MC, van der Meulen J, McIntosh G, Gillatt D, Emberton M. Threshold volumes for urological cancer surgery: a survey of UK urologists. *BJU Int* 2004; **94**: 1010–3
- 11 Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA* 1998; **280**: 1690–1
- 12 National Cancer for Health Statistics. National Hospital Discharge Survey, 2004. Available at: ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Datasets/NHDS/nhds04/. Accessed September 2006
- 13 Mettlin C. The American Cancer Society National Prostate Cancer Detection Project and National patterns of prostate cancer detection and treatment. *CA Cancer J Clin* 1997; **47**: 265–72
- 14 Penson DF, McLerran D, Feng Z *et al.* 5-year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study. *J Urol* 2005; **173**: 1701–5
- 15 Holm T, Johansson H, Cedermark B, Ekelund G, Rutqvist LE. Influence of hospital- and surgeon-related factors on outcome after treatment of rectal cancer with or without preoperative radiotherapy. *Br J Surg* 1997; **84**: 657–63
- 16 Gee WF, Holtgrewe HL, Albertsen PC *et al.* Subspecialization, recruitment and retirement trends of American urologists. *J Urol* 1998; **159**: 509–11
- 17 Adams AS, Soumerai SB, Lomas J, Ross-Degnan D. Evidence of self-report bias in assessing adherence to guidelines. *Int J Qual Health Care* 1999; **11**: 187–92
- 18 Flum DR, Salem L, Elrod JA, Dellinger EP, Cheadle A, Chan L. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA* 2005; **294**: 1903–8
- 19 Schrag D, Earle C, Xu F *et al.* Associations between hospital and surgeon procedure volumes and patient outcomes after ovarian cancer resection. *J Natl Cancer Inst* 2006; **98**: 163–71
- 20 Marcus AD. Prostate surgery preserves potency, but HMOs are putting up barriers. *Wall Street Journal* June 19, 2002

Correspondence: Thomas Denberg, 4200 E. 9th Ave., B-180, Division of General Internal Medicine, University of Colorado at Denver and Health Sciences Center, Denver, Colorado 80262, USA.
e-mail: tom.denberg@uchsc.edu

Abbreviations: RP, radical prostatectomy; AMA, American Medical Association; CBSA, Census Core Based Statistical Area.

Marriage and Ethnicity Predict Treatment in Localized Prostate Carcinoma

Thomas D. Denberg, M.D., Ph.D.^{1,2}

Brenda L. Beaty, M.S.P.H.²

Fernando J. Kim, M.D.³

John F. Steiner, M.D., M.P.H.^{1,2}

¹ Division of General Internal Medicine, Department of Medicine, University of Colorado Health Sciences Center, Denver, Colorado.

² Colorado Health Outcomes Program, University of Colorado Health Sciences Center, Denver, Colorado.

³ Department of Urology, Denver Health Medical Center, University of Colorado Health Sciences Center, Denver, Colorado.

Supported in part by a Redes en Acción research subcontract from the Baylor College of Medicine, funded by a Special Populations Network NCI grant (U01CA86117), Amelie G. Ramirez, Dr.PH (PI).

The authors acknowledge the efforts of the Applied Research Program, National Cancer Institute; the Office of Research, Development and Information, Centers for Medicare and Medicaid Services (CMS); Information Management Services (IMS), Inc.; and the Surveillance, Epidemiology, and End Results (SEER) Program tumor registries in the creation of the SEER-Medicare database.

This study used the linked SEER-Medicare database. The interpretation and reporting of these data are the sole responsibility of the authors.

Address for reprints: Thomas D. Denberg, M.D., Ph.D., Division of General Internal Medicine, Department of Medicine, University of Colorado Health Sciences Center, 4200 East 9th Avenue, B-180, Denver, CO 80262; Fax: (303) 372-9092; E-mail: tom.denberg@uchsc.edu

Received July 19, 2004; revision received September 24, 2004; accepted December 20, 2004.

BACKGROUND. Primary treatment for early-stage prostate carcinoma includes expectant management or, for curative intent, radical prostatectomy or radiotherapy. Treatment recommendations are generally guided by clinical factors such as Gleason grade, prostate-specific antigen level, comorbid illnesses, and patient age. Sociocultural factors may also have influences on patient and urologist treatment choices.

METHODS. The authors used bivariate and multinomial logistic regression to identify medical and sociodemographic predictors of prostatectomy (compared with radiotherapy) and curative therapy (compared with expectant management) in a cohort of 27,920 non-Latino white, black, and Latino men without comorbidities in the latest linked Surveillance, Epidemiology and End Results–Medicare dataset (years 1995–1999). Predictors included tumor stage, patient age, marital status, race/ethnicity, and socioeconomic status.

RESULTS. Younger age and higher tumor grade were robust predictors of curative treatment compared with expectant management and of prostatectomy compared with radiotherapy. Sociodemographic factors had an additive role in treatment choice. Marriage predicted curative treatment compared with expectant management (adjusted risk ratio [RR] = 1.28 [1.25–1.30]) and prostatectomy compared with radiotherapy (adjusted RR = 1.24 [1.20–1.28]). Although blacks and Latinos were just as likely as whites to receive curative treatment, blacks were significantly less likely, whereas Latinos were more likely, to receive prostatectomy compared with radiotherapy (adjusted RRs = 0.77 [0.72–83]) and 1.24 [1.18–1.30], respectively).

CONCLUSIONS. Marriage was positively associated with curative treatment in general, and with prostatectomy specifically. Blacks received prostatectomy less often than whites, although they did not receive less curative treatment overall. Latinos received prostatectomy more often than whites. Clinicians should recognize the importance of cultural and social forces as well as biomedical factors in decisions regarding the treatment of patients with early-stage prostate carcinoma. *Cancer* 2005;103:1819–25. © 2005 American Cancer Society.

KEYWORDS: prostate carcinoma, localized disease, informed decision-making, treatment patterns, health disparities, marriage.

Prostate carcinoma is the leading cancer affecting men of all races in the U.S., and is the second most common cause of cancer death. After the introduction of the prostate-specific antigen (PSA) test in 1987, widespread screening led to a dramatic increase in the identification of patients with early-stage prostate carcinoma. With this diagnosis, many men face considerable challenges regarding treatment. In part, this is because of a lack of randomized trial evidence clearly favoring a mortality benefit for any of the main curative forms of treatment, including radical prostatectomy, exter-

nal-beam radiotherapy, and brachytherapy. In addition, each of these curative options carries a high risk of late side effects, such as incontinence, impotence, and bowel urgency.¹ Many men have difficulty deciding whether they can accept such risks. These difficulties are most acute among men healthy enough to have choices, whereas older and sicker men are less able to tolerate surgery, and therefore have fewer options. Indeed, because of a lack of clear-cut mortality benefit, there is also controversy regarding the merits of curative therapy versus expectant observation (sometimes known as "watchful waiting"). In summary, for men healthy enough to have treatment choices, the first decision is usually between prostatectomy and a form of radiotherapy. Another crucial choice, especially as men grow older, is between curative treatment and expectant management. In the face of such decisions, social and cultural factors may have an influence over and above purely biomedical considerations.

We hypothesized that sociocultural factors would add to the explanatory power of traditional clinical variables, such as tumor grade, PSA level, comorbid illnesses, and patient age, in predicting treatment choice in nonmetastatic prostate carcinoma. Previous studies²⁻⁶ have identified several such factors, including race/ethnicity, socioeconomic status (SES), and geographic region. Almost all studies have revealed significant regional variations in treatment patterns and substantially lower rates of prostatectomy among blacks compared with whites, possibly due to provider differences, patient preferences, or health care access barriers that constrain treatment choices. In the current study, we assess whether a number of clinical and sociodemographic variables predict treatment choice in a population of Medicare enrollees without documented comorbid illnesses. These healthier men have the greatest number of treatment options because the costs of their care are covered by Medicare. Our analysis employs the latest linked Surveillance, Epidemiology and End Results (SEER) cancer registry and Medicare inpatient records (1995-1999), and we include marital status and Latino ethnicity, variables that have not been assessed consistently in previous studies.

MATERIALS AND METHODS

Data Sources

We tested our hypotheses that particular clinical and sociodemographic characteristics predict receipt of 1) prostatectomy compared with some form of radiotherapy (external beam or brachytherapy) as well as 2) either form of curative therapy (prostatectomy or radiotherapy) compared with expectant management by

using data from the SEER cancer registries that have been linked with Medicare hospital-discharge records. We focused our analyses on a subset of men > 65 who do not have any documented comorbidities and are, therefore, likely to be among the healthiest in the database, with the greatest number of treatment options and opportunities to make treatment decisions that are informed by a consideration of risks and benefits. The SEER-Medicare dataset has been used in several other studies to assess patterns of care for newly diagnosed patients with cancer of several sites, and its strengths and limitations for this purpose were recently reviewed.⁷ Covering approximately 14% of the U.S. population, the SEER registries, sponsored by the National Cancer Institute (NCI), document all incident cases of cancer in 6 urban areas (San Francisco-Oakland, San Jose, Los Angeles county, Seattle, Atlanta, and Detroit) and in 5 states (Connecticut, Hawaii, Iowa, New Mexico, and Utah). In the linked dataset, SEER includes patient age and date of diagnosis; tumor location, grade, stage, and lymph node involvement; therapy received within 4 months of diagnosis; and sociodemographic characteristics including race/ethnicity, marital status, and a variety of census-based SES measures as proxies for individual-level data not collected by SEER.

The Medicare program provides health coverage for 97% of persons ≥ 65 and collects claims for all program services. Hospitalization data, included in the Medicare Provider Analysis and Review (MEDPAR) files, contains information on all hospitalizations since 1984, including admission and discharge diagnoses and comorbid conditions.

The SEER and Medicare databases were linked to allow population-based studies of health outcomes. Data for 94% of persons ≥ 65 in SEER have been linked successfully to Medicare records. Use of the combined dataset excluded approximately 22% of prostate carcinoma cases in SEER, primarily among men < 65 and those enrolled in Health Maintenance Organizations. The remaining, linked cases, however, allowed for adjustment by comorbid conditions and eliminated the confounding effects of insurance coverage. The research described here was approved by the Colorado multiple institutional review board.

Study Participants

Non-Latino white, black, and Latino men with localized prostate carcinoma were included if there were matching SEER and Medicare records and the diagnosis was not made at autopsy or on a death certificate. We included all cases between the years 1995 and 1999, the most recent data available in SEER-Medicare and not analyzed in previous studies. Subjects were

excluded if, at the time of diagnosis, they had one or more (nonprostate carcinoma) comorbidities or if data pertaining to patient age or tumor stage or grade were unavailable ($n = 25,311$). Based on these criteria, 27,290 patients were included in the current study.

Primary Treatment and Tumor Characteristics

Primary treatment was based on SEER data. In order of priority, primary treatment was defined as prostatectomy if any form of curative-intent prostatectomy was indicated by the site-directed surgery variable (transurethral resection of the prostate [TURP] procedures were excluded), as radiotherapy if indicated by any form of external-beam radiotherapy or brachytherapy, and as watchful waiting if neither of these was obtained. A variable indicating any form of curative treatment was assigned a true value if treatment included either surgery or radiotherapy.

Tumor stage was based on the SEER/American Joint Commission on Cancer extent of disease (EOD; 10 prostate pathology ext 1995+) variable corresponding to localized (T1 or T2) disease. Clinical as opposed to pathologic staging was utilized except that when the former was unavailable and prostatectomy was performed, staging was assumed to be localized because surgery is typically not indicated for clinically advanced disease. For patients who did not receive prostatectomy, staging was based only on biopsy results and radiologic criteria rather than on complete excision. In some cases, this underrepresented the true EOD but did reflect the clinical staging used to determine treatment. Tumor grade was trichotomized as low, moderate, and high (i.e., Grades 1, 2, and 3/4, respectively), corresponding to Gleason scores 2–4, 5–7, and 8–10. PSA scores were not included because these were unavailable in the SEER-Medicare database.

Demographic Characteristics and Coexisting Illnesses

Information on race and age at diagnosis was obtained from the SEER database. The SES of each patient was based on year 2000 census data. Zip code measures were utilized only if census-tract data were unavailable (21% of patients). SES measures included per capita income, percent of residents living below the poverty level (race and age specific), percent of persons ≥ 25 years with less than a high school education (race specific), and percent of persons ≥ 65 years not speaking English well. These variables were necessarily ecologic as opposed to individual-level measures. Because they were all highly correlated, we selected educational level to capture SES. Marital status was based on SEER (dichotomized as married vs. not married/unknown).

Comorbidity scores were derived from MEDPAR records, using the Deyo adaptation⁸ of the Charlson comorbidity index and calculated by means of a SAS macro (SAS Institute Inc., Cary, NC) available on the NCI SEER-Medicare website. All patients with scores > 0 were excluded from further analysis. If a patient received prostatectomy, we included all MEDPAR records through the date of this procedure. Otherwise, we included all MEDPAR records through the first hospitalization occurring within 6 months of the diagnosis. If there were no MEDPAR records before the diagnosis, the comorbidity score was assumed to be zero.

Statistical Analysis

Using bivariate analysis, we examined separately the association between 1) prostatectomy versus a form of radiotherapy, and 2) either form of curative therapy (prostatectomy or radiotherapy) versus expectant management and the following variables: patient age, tumor stage, tumor grade, race/ethnicity, marital status, per capita income, poverty level, educational attainment, and poor use of English. Descriptive analyses and multiple logistic regression models were conducted with SAS software. The outcome variables were dichotomous: 1) prostatectomy versus radiotherapy and 2) curative therapy (prostatectomy or radiotherapy) versus expectant management. We determined a priori that the independent variables in the logistic models would be those significantly associated with initial therapy in the bivariate analyses, using a statistical significance level of 0.05. We also examined statistical interactions of age and grade, race and grade, age and marriage, age and race, age and non-high school education, race and marriage, and race and non-high school education. Results of the logistic regression models are shown as percentages of patients by race/ethnicity receiving the treatment of interest and risk ratios (RRs) associated with each independent variable adjusted for the others. RRs were computed as corrections of the adjusted odds ratios.⁹

RESULTS

The sociodemographic and clinical characteristics of the study cohort (84.4% white, 9.9% black, 5.7% Latino) are shown in Table 1. Differences by race/ethnicity were evident. Blacks were much less likely than whites and Latinos to be married. Compared with whites, blacks and Latinos were increasingly likely to live in low SES areas, as reflected by the percentage of census-tract/zip code inhabitants who had not graduated from high school. Eighty-five percent of Latino men had tumors graded as moderately or poorly differentiated compared with 89% of white

TABLE 1
Sociodemographic and Clinical Characteristics of 27,290 Men with Early-Stage Prostate Carcinoma and No Comorbidities in SEER-Medicare, 1995–1999^a

Cohort	Married	SES			Tumor grade			Treatment		
		High	Mod	Low	Low	Mod	High	RP	XRT	WW
All ages										
All (<i>n</i> = 27,290)	75	48	31	21	11	70	20	37	30	32
White (<i>n</i> = 23,040)	77	55	33	12	11	70	19	38	30	32
Black (<i>n</i> = 2698)	58	13	25	62	8	71	21	30	35	35
Latino (<i>n</i> = 1552)	73	5	9	87	15	65	20	45	21	35
Age < 70 yrs										
All (<i>n</i> = 11,107)	77	47	31	22	9	73	18	61	23	16
White (<i>n</i> = 9011)	80	56	33	11	9	74	17	63	22	15
Black (<i>n</i> = 1375)	59	14	27	58	7	72	21	45	33	22
Latino (<i>n</i> = 721)	75	4	8	88	14	67	19	64	15	20
Age ≥ 70 yrs										
All (<i>n</i> = 16,183)	73	48	31	21	12	67	21	21	35	44
White (<i>n</i> = 14,029)	74	54	33	12	12	67	21	22	36	43
Black (<i>n</i> = 1323)	57	11	23	66	9	69	22	14	37	49
Latino (<i>n</i> = 831)	71	5	9	86	15	63	22	28	26	47

SEER: Surveillance, Epidemiology and End Results program; SES: socioeconomic status; Mod: moderate; RP: radical prostatectomy; XRT: external beam radiotherapy or brachytherapy; WW: conservative management ("watchful waiting").

^a All numbers are rounded percentages. Married refers to percentage of men currently married. SES (socioeconomic status) refers to the percentage of sample residing in census-tract/zip code areas where 0–10%, 11–20%, and ≥ 21% of inhabitants ≥ 25 years have less than a high school education. Grade corresponds to Gleason score (Low/well differentiated = 2–4; Med/moderately differentiated = 5–7; High/poor or undifferentiated = 8–10). Treatment refers to the percentage of men who received as primary treatment (mutually exclusive) radical prostatectomy (RP), any form of external beam radiotherapy or brachytherapy (XRT), or conservative management (WW).

TABLE 2
Receipt of Prostatectomy and Curative Therapy (Prostatectomy or Radiotherapy^a) by Race/Ethnicity and Marital Status

Race/ethnicity	White			Black			Latino		
	Unmarried	Married	<i>P</i> value ^b	Unmarried	Married	<i>P</i> value	Unmarried	Married	<i>P</i> value
Age < 70 <i>n</i> = 11,107									
Prostatectomy	49%	66%	< 0.001	37%	51%	< 0.001	49%	69%	< 0.001
Any curative therapy	76%	87%	< 0.001	74%	80%	0.007	71%	83%	0.008
Age ≥ 70 <i>n</i> = 16,183									
Prostatectomy	13%	24%	< 0.001	11%	16%	0.007	23%	29%	0.09
Any curative therapy	44%	62%	< 0.001	46%	55%	0.005	43%	57%	0.001

^a Radiotherapy refers to any external-beam radiotherapy or brachytherapy.

^b The *P* value was determined using the chi-square test.

men and 92% of black men. Black men were much less likely than white men to receive prostatectomy (30% vs. 38%), whereas Latino men were much more likely than white men to receive prostatectomy (45% vs. 38%). There was, however, little difference in receipt of either form of curative therapy (compared with expectant management) among whites, blacks, and Latinos (68%, 65%, and 66%, respectively).

Younger men (age < 70) received curative-intent therapy 84% of the time, with prostatectomy predominating for 73% of these men (i.e., 61% of the total). A higher percentage of married men compared with un-

married men received any form of curative therapy (86% vs. 75%) as well as prostatectomy, specifically (65% vs. 47%; data not shown). Blacks were less likely than whites to receive any form of curative therapy (78% vs. 85%) as well as prostatectomy, specifically (45% vs. 63%). whereas, among Latinos, there was greater parity with whites (79% vs. 85% and 64% vs. 63%, respectively). Table 2 depicts higher utilization of curative therapy in general, and of prostatectomy compared with radiotherapy among married men in all three racial/ethnic groups. The effect was most pronounced among younger, married Latinos, who

TABLE 3
Summary of Logistic Regression Predicting Prostatectomy versus Radiotherapy^a

Variable/model	Overall	White	Black	Latino
Total no. of patients	18,444	15,685	1743	1016
No. of patients (%) receiving prostatectomy	10,189 (55%)	8690 (55%)	806 (46%)	693 (68%)
Age (yrs) ≥ 70 vs. < 70	0.50 (0.48–0.52)	0.51 (0.48–0.53)	0.47 (0.40–0.54)	0.63 (0.55–0.72)
Tumor grade				
Moderate vs. low	1.21 (1.14–1.27)	1.18 (1.11–1.25)	1.68 (1.27–2.09)	1.26 (1.08–1.41)
High vs. low	1.29 (1.22–1.36)	1.26 (1.18–1.33)	1.81 (1.37–2.25)	1.31 (1.11–1.46)
			$P = 0.003$	$P = 0.005$
Married vs. unmarried	1.24 (1.20–1.28)	1.24 (1.20–1.29)	1.25 (1.12–1.38)	1.13 (1.01–1.23)
Percentage of persons with < 12 yrs of education				
11–20 vs. 0–10	0.95 (0.92–0.99)	0.96 (0.92–0.99)	0.86 (0.71–1.00)	NS
≥ 21 vs. 0–10	0.94 (0.91–1.00)	0.95 (0.90–1.00)	0.83 (0.69–0.96)	
	$P = 0.008$	$P = 0.015$	$P = 0.04$	
Race				
Black vs. white	0.77 (0.72–0.83)			
Latino vs. white	1.24 (1.18–1.30)	—	—	—

NS: not significant.

^a Radiotherapy includes external-beam radiotherapy or brachytherapy. Risk ratios—all variables are significant at $P < 0.0001$, except where noted.

TABLE 4
Summary of Logistic Regression Predicting any Form of Curative Therapy^a

Variable/model	Overall	White	Black	Latino
Total no. of patients	27,290	23,040	2698	1552
No. of patients (%) receiving curative treatment	18,444 (68%)	15,685 (68%)	1743 (65%)	1016 (65%)
Age (yrs) ≥ 70 vs. < 70	0.67 (0.65–0.69)	0.67 (0.65–0.69)	0.66 (0.60–0.71)	0.65 (0.58–0.73)
Tumor grade				
Moderate vs. low	1.60 (1.56–1.64)	1.60 (1.55–1.64)	1.49 (1.34–1.63)	1.76 (1.59–1.91)
High vs. low	1.56 (1.52–1.61)	1.58 (1.53–1.63)	1.33 (1.16–1.50)	1.73 (1.52–1.90)
Married vs. unmarried	1.28 (1.25–1.30)	1.30 (1.28–1.33)	1.13 (1.07–1.19)	1.27 (1.16–1.36)
Percentage of persons with < 12 yrs of education				
11–20 vs. 0–10	0.95 (0.93–0.97)	0.94 (0.92–0.97)		
≥ 21 vs. 0–10	0.91 (0.89–0.94)	0.92 (0.89–0.95)	NS	NS
Race				
Black vs. white	0.96 (0.93–0.99)			
Latino vs. white	1.00 (0.96–1.04)			
	$P = 0.04$			

NS: not significant.

^a Curative therapy includes prostatectomy or radiotherapy (external-beam radiotherapy or brachytherapy). Risk ratios—all variables are significant at $P < 0.0001$ unless otherwise noted.

had 20% more prostatectomies than their unmarried counterparts.

Among older men (age ≥ 70), 56% received a form of curative therapy, with radiotherapy predominating 63% of the time (i.e., 35% of the total). As in the younger cohort, a higher percentage of married compared with unmarried men in the older cohort received any form of curative therapy (61% vs. 44%) as well as prostatectomy, specifically (24% vs. 14%; data not shown). Blacks were less likely than whites to receive any form of curative therapy (51% vs. 58%) as well as prostatectomy, specifically (14% vs. 22%), whereas Latinos and whites were more similar (54%

vs. 58% and 28% vs. 22%, respectively; data not shown). A positive association between marriage and higher rates of prostatectomy and either form of curative therapy applied within all race/ethnic groups (Table 2). However, compared with the younger cohort, the association was less pronounced for prostatectomy, specifically, and somewhat more pronounced for any form of curative therapy.

In bivariate analyses, age, race/ethnicity, marriage, high school education, and tumor grade were predictive of prostatectomy and any form of curative therapy ($P < 0.0001$). However, none of the interaction terms was significant. The results of the multivariate

analyses are displayed in Tables 3 and 4, showing as relative risks the adjusted predictors of prostatectomy versus radiotherapy and curative therapy versus expectant management, respectively. As expected, younger age and higher tumor grade were strong predictors of prostatectomy compared with radiotherapy, and of curative treatment compared with expectant management. Marriage was also a strong predictor of prostatectomy and curative treatment (prostatectomy or radiotherapy) in all racial/ethnic groups. Black race was negatively associated, and Latino ethnicity was positively associated, with receipt of prostatectomy, although there were no racial/ethnic differences in receipt of curative treatment overall. Lower SES predicted lower rates of prostatectomy compared with radiotherapy among blacks. Finally, we performed a subgroup analysis in the four California and New Mexico registries because Latinos are concentrated in these areas and because we wanted to exclude regional variation in procedure utilization as a possible explanation for significant differences between Latinos and whites. The results were not significantly different from those in the overall sample.

DISCUSSION

The current study confirmed the hypothesis that sociocultural factors add significant explanatory power to traditional biomedical variables in understanding treatment patterns of early-stage prostate carcinoma. We analyzed a national sample of non-Latino white, black, and Latino Medicare beneficiaries who had no documented comorbid conditions between the years 1995 and 1999. This population is highly likely to face therapeutic options after diagnosis, including prostatectomy, external-beam radiotherapy, brachytherapy, and expectant management. We found, as anticipated, that younger age and higher tumor grade were very strong predictors of treatment. In addition to these biomedical influences, however, we also found that several sociocultural variables, such as marital status, high school education, and race/ethnicity, were also significant predictors of treatment.

That blacks were no less likely than whites to receive curative therapy, but were less likely to undergo prostatectomy compared with radiotherapy is intriguing for two reasons. First, almost all patients see urologists for confirmatory biopsies and, second, urologists in general are more likely to recommend prostatectomy rather than radiotherapy for curative intent.¹⁰ It is possible that physicians recommend surgery less often to their black compared with white patients because they perceive black men at higher risk for poor outcomes³ and also less likely to adhere to medical advice.¹¹ The beliefs and preferences of black patients must also be considered,

and could include distrust of physicians and fear of surgery,¹² more concerns about impotence,¹³ and more pessimism than other racial groups about the curability of prostate carcinoma.¹⁴ Finally, some urologists may downplay surgery as an option because of a priori assumptions that their black patients have these sorts of concerns.

Our finding of a higher rate of prostatectomy among Latinos compared with whites was somewhat surprising. Two previous studies, using cancer registry data through 1994, found either significantly lower⁵ or no difference⁶ in prostatectomy rates among Latinos. Neither of these studies adjusted for comorbidities or measures of SES, however, and both included a large proportion of men < 65. A third investigation,² based on 1994–1995 prostate cancer outcomes study data but also using a younger population than the one in the current study, derived results similar to our own. One possibility is that Latinos, many of whom live in rural areas or in Spanish-speaking enclaves, have less real or perceived access to radiotherapy oncology services. Alternatively, Latinos may have more favorable attitudes towards surgery (or more fear of radiotherapy) compared with whites and blacks, or perhaps they have a greater trust in the authority of physicians and, therefore, more willingness to accept prostatectomy when it is recommended.

A particularly noteworthy finding was that marital status appears to be at least as strong a predictor of prostatectomy as race/ethnicity, which has received the greatest attention in previous studies. The first study to identify higher utilization of prostatectomy among married men was conducted in 2000.⁵ Two subsequent studies^{2,3} showed that unmarried men received more conservative therapy. It is possible that married men (or their wives) advocate therapy that they perceive as likeliest to yield cure, whereas unmarried men are more likely to lack social supports that would encourage aggressive interventions. The influence of wives on the selection of curative therapy has some plausibility, based on a qualitative study of patients with early-stage prostate carcinoma in which wives were more interested in their husbands' cure whereas husbands tended to place greater emphasis on treatment side effects.¹⁵ Finally, perhaps clinicians recommend aggressive therapy more strongly to married than unmarried men.

Given the current emphasis on improving the quality of patient involvement in decision-making, the role of spouses deserves greater attention. Little is known, for example, about how often wives accompany their husbands to the clinic, and about how their presence influences consultations. Wives may enhance the quality of decision-making by gathering information, coaching the patient to ask questions, or advising about treatment.¹⁶

Conversely, even informed spouses have the potential to impair decision-making. One study found that in consultations that include the physician, patient, and spouse, patients frequently raise fewer topics, are less assertive, engage in less shared decision-making, and are frequently excluded from conversations.¹⁷

The current study has several limitations. Provider characteristics, referral patterns, and patient/spouse preferences could not be analyzed, and ecologic rather than individual measures of SES were utilized. If there was preferential underascertainment of comorbid conditions in more socially disadvantaged groups, this would have inflated the strength of association between treatment and marital status, SES, and race/ethnicity. Regional variation in practice patterns might also influence findings of racial/ethnic differences in treatment.⁴ However, our findings pertaining to black men are consistent with those of previous studies that controlled for registry, and a subgroup analysis performed for Latinos concentrated in California and New Mexico did not differ significantly from results obtained in the overall sample. In addition, although the sensitivity and specificity of a designation of Latino ethnicity is unknown in the SEER-Medicare database,¹⁸ we believe misclassification is unlikely to have been a major concern in our analysis. SEER race recode B is more exact than Medicare,¹⁸ whereas Medicare appears to misreport Latino ethnicity $\leq 10\%$ of the time.¹⁹ Finally, it should be noted that a strength of our study compared with previous research involved the inclusion of clinicopathologic staging information in the SEER-Medicare dataset beginning in 1995, thereby reducing the frequency of clinical upstaging based on surgical pathology.

As clinical uncertainty continues to surround the optimal treatment of early-stage disease, and as patient involvement in decision-making remains a key goal for ethical and quality-of-life considerations, the results of the current analysis suggest several important avenues of inquiry. How, for example, do spouses influence the nature and quality of decision-making and how might clinicians productively facilitate their involvement in this process? Do patients in certain racial/ethnic groups manifest particular beliefs and attitudes about cancer and medical therapies that complicate their ability to rationally weigh risks and benefits? Finally, which patient groups lack access to radiotherapy oncology? Assessing and ensuring the adequacy of shared decision-making in this very complex clinical scenario will depend on finding answers to these and related questions.

REFERENCES

1. Potosky AL, Davis WW, Hoffman RM, et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the prostate cancer outcomes study. *J Natl Cancer Inst.* 2004;96(18):1358–1367.

2. Harlan LC, Potosky A, Gilliland FD, et al. Factors associated with initial therapy for clinically localized prostate cancer: prostate cancer outcomes study. *J Natl Cancer Inst.* 2001; 93(24):1864–1871.
3. Hoffman RM, Harlan LC, Klabunde CN, et al. Racial differences in initial treatment for clinically localized prostate cancer. Results from the prostate cancer outcomes study. *J Gen Intern Med.* 2003;18(10):845–853.
4. Klabunde CN, Potosky AL, Harlan LC, et al. Trends and black/white differences in treatment for nonmetastatic prostate cancer. *Med Care.* 1998;36(9):1337–1348.
5. Lai S, Lai H, Krongrad A, et al. Radical prostatectomy: geographic and demographic variation. *Urology.* 2000;56(1):108–115.
6. Morris CR, Snipes KP, Schlag R, et al. Sociodemographic factors associated with prostatectomy utilization and concordance with the physician data query for prostate cancer (United States). *Cancer Causes Control.* 1999;10(6):503–511.
7. Warren JL, Klabunde CN, Schrag D, et al. Overview of the SEER-Medicare data: content, research applications, and generalizability to the United States elderly population. *Med Care.* 2002;40(8 Suppl.):IV-3–IV-18.
8. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol.* 1992;45(6):613–619.
9. Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA.* 1998;280(19):1690–1691.
10. Fowler FJ Jr., McNaughton Collins M, Albertsen PC, et al. Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer. *JAMA.* 2000;283(24):3217–3222.
11. van Ryn M, Burke J. The effect of patient race and socioeconomic status on physicians' perceptions of patients. *Soc Sci Med.* 2000;50(6):813–828.
12. Shankar S, Selvin E, Alberg AJ. Perceptions of cancer in an African-American community: a focus group report. *Ethn Dis.* 2002;12(2):276–283.
13. Demark-Wahnefried W, Strigo T, Catoe K, et al. Knowledge, beliefs, and prior screening behavior among blacks and whites reporting for prostate cancer screening. *Urology.* 1995;46(3):346–351.
14. McCoy CB, Anwyll RS, Metsch LR, et al. Prostate cancer in Florida: knowledge, attitudes, practices, and beliefs. *Cancer Pract.* 1995;3(2):88–93.
15. O'Rourke ME. Narrowing the options: the process of deciding on prostate cancer treatment. *Cancer Invest.* 1999;17(5):349–359.
16. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med.* 1997;44(5):681–692.
17. Greene MG, Majerovitz SD, Adelman RD, et al. The effects of the presence of a third person on the physician-older patient medical interview. *J Am Geriatr Soc.* 1994;42(4):413–419.
18. Bach PB, Guadagnoli E, Schrag D, et al. Patient demographic and socioeconomic characteristics in the SEER-Medicare database applications and limitations. *Med Care.* 2002;40(8 Suppl.):IV-19–IV-25.
19. Escarce JJ, McGuire TG. Methods for using Medicare data to compare procedure rates among Asians, blacks, Hispanics, Native Americans, and whites. *Health Serv Res.* 2003;38(5): 1303–1317.

Patient Treatment Preferences in Localized Prostate Carcinoma

The Influence of Emotion, Misconception, and Anecdote

Thomas D. Denberg, MD, PhD
Trisha V. Melhado, BS
John F. Steiner, MD, MPH

Department of Medicine, Division of General Internal Medicine and Colorado Health Outcomes Program, University of Colorado at Denver and Health Sciences Center, Denver, Colorado

We acknowledge the editorial assistance of Richard Hoffman, MD, MPH (University of New Mexico, Division of General Internal Medicine). In addition, Robert Donohue, MD (Department of Urology, University of Colorado at Denver and Health Sciences Center and Denver Veterans Affairs Medical Center) helped to facilitate the patient interviews.

Supported by R03-99505 from the National Cancer Institute.

Address for reprints: Thomas D. Denberg, MD, Ph.D., Division of General Internal Medicine, University of Colorado Health Sciences Center, 4200 E. ninth Avenue, B-180, DGIM/UCHSC, Denver, CO 80262, USA; E-mail: tom.denberg@uchsc.edu

Received December 21, 2005; accepted March 27, 2006.

BACKGROUND. Multiple therapeutic options exist for localized prostate carcinoma, without conclusive evidence to guide the choice of treatment. Thus, treatment should reflect trade-offs between the probability of curing disease and the desire to avoid treatment-associated side effects. Factors that actually influence patient treatment preferences are poorly understood.

METHODS. We reviewed medical records and carried out in-depth, semistructured interviews of 20 men with newly-diagnosed, clinically-localized prostate carcinoma in a Veterans Affairs Hospital following their first consultations with urologists and before treatments were initiated. Six to eight months after treatment, we carried out follow-up interviews. Interviews explored beliefs and attitudes about prostate cancer and treatment options, emotional reactions to the diagnosis, treatment preferences, information sources, and perceptions of interactions with urologists.

RESULTS. Patient treatment preferences were not based on careful assessments of numerical risks for various clinical outcomes. Instead, feelings of fear and uncertainty contributed to a desire for rapid treatment, and specific preferences were profoundly influenced by misconceptions, especially about prostatectomy, and by anecdotes about the experiences of others with cancer. Few patients wanted to seek second opinions. Most patients received treatments that matched their initial preferences. Afterwards, they justified their choices in terms of the same misconceptions and anecdotal influences invoked during treatment deliberation.

CONCLUSIONS. For men with localized prostate carcinoma, the treatment decision-making process would benefit from interventions that moderate feelings of fear and a desire for rapid treatment, dispel common and powerful misconceptions about prostate cancer and its therapies, and help patients avoid over-reliance on anecdotes. *Cancer* 2006;107:620–30. © 2006 American Cancer Society.

KEYWORDS: localized prostate carcinoma, treatment, decision-making.

In localized prostate cancer, definitive therapy includes radical prostatectomy, external beam radiation, brachytherapy, and cryotherapy. Optimal treatment, however, is unknown because there is a lack of convincing evidence regarding which form of therapy offers the best long-term survival. Moreover, all forms of therapy have unique and potentially serious side effects. Indeed, despite at least one recent report,¹ questions remain about whether the morbidities associated with radical prostatectomy are worth the small potential benefits in overall survival when compared with watchful waiting, especially for low- and intermediate-grade disease.^{2,3} Ultimately, decisions about how to treat localized prostate cancer are highly

personal. Ideally, each patient would base his decision on accurate information, weighing all options in terms of the likelihood for tumor recurrence, personal preferences for avoiding specific treatment-related side effects, and pragmatic considerations such as cost, convenience, and requirements for follow-up care.

Little is known about how men diagnosed with localized prostate carcinoma choose their treatment. Studies using hypothetical patients, retrospective data, or non-U.S. populations have examined discrete influences on and correlates of decision-making, such as social supports, informational sources, demographic characteristics, and concerns about side effects and posttreatment quality of life.^{4–19} Some of these studies have utilized focus group and individual patient interviews to aid in the development of surveys and psychometric instruments but most have asserted conclusions without reporting the content of the actual interviews. There is also a small literature based on testimonials of predominately white, socially privileged men that recount odysseys of receiving a prostate cancer diagnosis, agonizing over what to do, and traversing perplexing health care systems.^{20–22} Because the topic has not been adequately addressed in the prior literature this study aims to describe, from the perspective of working- and middle-class patients themselves, how they make treatment decisions in real time following the diagnosis of localized prostate carcinoma.

MATERIALS AND METHODS

Qualitative research methods are well-suited for studying the complex and dynamic experience of decision-making following a cancer diagnosis because they permit rich descriptions using the words and categories of participants themselves.²³ When phenomena are poorly understood, qualitative methods aid in the identification of key variables and can generate informed hypotheses for evaluation in subsequent, quantitative studies. Qualitative methods can also furnish novel ideas about how to target the improvements in health services delivery.

Participants

Patients were identified through the Denver Veterans Affairs Medical Center Urology Outpatient Practice. Clinic personnel confirmed patient eligibility for the study. Criteria included men (≤ 80 years, English-speaking), with clinically localized (i.e. T1 or T2) prostate cancer, who had been diagnosed within the previous six weeks and had not yet received treatment.

Description of Setting and Procedures

We carried out individual patient interviews within a week of, and typically on the same day as, a patient's first treatment discussion with a urology resident. Four urology residents beyond their second year of training rotated through the service during the interview period. Each urologic consultation, lasting an average of 35 min, included a description of prostate cancer and the patient's unique tumor characteristics, a review of all major treatment options and their associated side effects, and prognostic information based on the Partin table.²⁴ Available forms of treatment included radical prostatectomy, external beam radiotherapy, brachytherapy (an option that requires Veterans Affairs-paid travel to Seattle) and, as noncurative therapy, hormonal ablation and watchful waiting. Cryotherapy was also an option, usually referenced as 'experimental,' but was not available within the institution. All patients were given an informational brochure that summarized this basic information.²⁵ Although clinical characteristics (e.g. patient age, PSA level, sexual activity, and comorbidities) were expected to influence the ways in which clinicians presented treatment options to patients, we did not study this phenomenon nor did we focus on the treatment options that might have been medically preferred given a patient's clinical profile. Instead, our goal was to characterize patients' attitudes and beliefs about the choices they actually faced as well as the strategies they used to decide on one form of treatment over another.

With three patients, we pilot-tested and refined a semistructured, in-depth interview that lasted between 60 and 90 min. An open-ended protocol allowed respondents to express themselves completely, in their own words, without the imposition of researcher-defined categories. The interviews, carried out by a medical anthropologist and qualitative research assistant, focused on the emotional repercussions of the diagnosis, perceived treatment options, treatment preferences and their rationale, knowledge of treatment-associated side effects, perceived changes in attitudes toward treatment before and after the urologic consultation, current and anticipated sources of information and advice, and perceptions of the urologist's treatment recommendations and advice about decision-making. Interviews were audio-taped and transcribed verbatim using numerical codes to protect patient identities. Researchers made no effort to influence treatment choices or judge their appropriateness. At the end of their first interview, patients were given \$25 as compensation for their participation. The final sample size was dictated by thematic saturation, which refers to the point at which additional interviews replicate previously-identified themes and fail to reveal

TABLE 1
Medical and Demographic Characteristics of Participants

Patient no.	Age (years)	Married	Education	Race/ethnicity	Gleason score	Clinical stage	PSA	Initial Treatment preference	Treatment received
1	55	+	Some HS	NLW	7	T2b	39.3	RP	RP
2	58	–	Some college	AA	7	T2b	17.0	RP	RP
3	61	–	HS graduate	NLW	7	T2b	7.1	RP	RP
4	63	+	HS graduate	NLW	7	T1c	7.8	RP>EBT	RP
5	64	+	College graduate	NLW	6	T1c	5.5	RP	RP
6	67	+	College graduate	NLW	6	T1c	6.7	RP	RP
7	69	+	Some college	NLW	6	T1c	7.2	RP	brachy
8	74	+	College graduate	NLW	5	T1c	5.0	RP	RP
9	53	+	Some college	AA	6	T1c	12.0	brachy	wants brachy
10	57	–	Some college	NLW	6	T2b	4.6	brachy	EBT, HA
11	63	+	Some college	NLW	6	T1c	5.5	brachy	brachy
12	57	–	Some college	AA	6	T2b	5.3	brachy>EBT	EBT
13	54	–	Some college	AA	6	T1c	10.6	EBT>brachy	EBT
14	58	+	HS graduate	AA	7	T2b	16.2	EBT	EBT, HA
15	69	+	Some HS	Latino	6	T1c	20.7	EBT	HA
16	70	+	Some college	NLW	7	T2b	7.5	EBT	EBT, HA
17	77	+	Some college	NLW	6	T2b	5.3	EBT	EBT
18	80	+	College graduate	NLW	6	T2b	9.7	ww	wants cryo
19	74	+	College graduate	NLW	6	T1c	14.8	unsure; ww possible	ww
20	69	+	College graduate	NLW	7	T2b	5.5	alternative tx ("Protosel")	Alternative tx

AA indicates African American; NLW, Non-Latino White; RP, radical prostatectomy; brachy, brachytherapy; EBT, external beam radiotherapy; HA, hormonal ablation; cryo, cryotherapy; ww, watchful waiting; "wants", at the time of the follow-up interview, treatment has not yet been received and the patient's treatment preference is indicated.

new findings. Chart reviews provided supplementary information about patient sociodemographics, medical history, tumor characteristics, and urologist notations regarding their discussions with patients. Six to eight months after the initial interviews, we audio-taped and transcribed 10- to 15-min follow-up telephone interviews to reassess patients' reasons for choosing the form of treatment they ultimately received.

Data Analysis

Using grounded-theory methodology,²⁶ the initial stage of data coding and interpretation involved two experienced qualitative researchers who carried out independent, methodical reviews of individual transcriptions in order to prepare summary documents of key thematic elements. Jointly, the investigators then reviewed these summaries along with the original transcriptions in order to produce consensus documents for each patient. This process involved comparing findings, discussing divergent coding, and resolving differences of interpretation when necessary. Finally, on the basis of the summary and consensus statements, the investigators used an iterative process to develop synopses of recurrent themes applicable to the entire sample.

This study was approved by the Colorado Multiple Institutional Review Board (COMIRB). In this study, informed Consent was obtained from All participants.

RESULTS

Participants

Thematic saturation was achieved with 20 participants. Table 1 summarizes their sociodemographic and medical characteristics, as well as treatment preferences and treatment received. Age of patients ranged from 54 to 80, with a mean of 65 years. Fifteen percent or 75% of patients were currently married; the remainder were widowed, divorced, never married, or had a noncohabiting partner. The majority of the sample (75%) was white; five (25%) were African-American. Educational attainment ranged from non-high-school to college graduates. All patients had intermediate grade, clinically localized prostate cancer. PSA scores ranged from 4.6 to 39.3, with a median score of 7.4. Common to most Veterans Administration populations, about half the patients had significant comorbidities. Nonetheless, all patients were eligible for at least two forms of potentially curative therapy meaning they had choices and faced treatment deci-

Fear and uncertainty (with denial)

It's cancer man! ...I try to sleep and get bad dreams... I don't know how much longer it's going to be for me, you know.

I think it's a time bomb and you don't know if your time is going to be short or time is going to be long... my worry is that it will spread into your lungs. Once cancer hits your lungs I think you are fodder, I think it's bye-bye baby...

I'm a little in shock because I had a couple of days of anxiety attacks. I don't know how much cancer I have. ...I should just try to retire as soon as I can before I just die off. ...But it's a slow-moving cancer so stop freaking yourself out. It's just not serious. All systems go. I'm kind of happy.

It upset me a little bit, but not a real lot. I've read there are quite a few different options as to how you can cure it and most of them are real successful. ...It's a real deadly thing. I know some people who have died from it.

Desire for rapid treatment (despite intellectual knowledge)

I'm worried... I don't want to wait. ...Even though I'm low-low I'd like to get it out of the way...We'll probably make a decision by today.

I always had it in my mind that I wanted the surgery before I even went to talk to {the doctor}. ...You don't wait once you know you got cancer – if you can get rid of it. ...They wanted to give me two weeks to think about it, but I didn't want to do that.

Thankfully, prostate cancer is not fast-moving. But...I think at times, there is that process, where the prostate cancer all of a sudden where it just blossoms. Does it always go slowly or can it go slowly and then all of a sudden explode?

People minimize the danger of having this cancer because they are told it is easily treated. Or that it is slow growing and all of these things. Yeah, a train doesn't look dangerous when it's going 5 mph but if it runs you over you'll be just as dead.

FIGURE 1. Patient quotes illustrating fear, uncertainty, and a desire for rapid treatment.

sions. Below, we describe their initial treatment preferences and the factors that influenced these.

Fear, Uncertainty, and a Desire for Rapid Treatment

For most patients, decision-making occurred within a very charged emotional context characterized by fear, uncertainty, and a desire for rapid treatment. After hearing news of the diagnosis, about two-thirds of patients acknowledged marked and persistent fear and uncertainty about the future. Patients younger than 70 were particularly likely to acknowledge fear (this applied to 13/16 such patients). Typically, expressions of fear were complemented at other times by its denial, seeming to reflect an internal dialogue aimed at convincing oneself that everything would be fine. Illustrative patient quotes are presented in Figure 1.

Almost all patients noted that prostate cancer tends to be slow-growing. Some patients mentioned that their own tumor characteristics, such as low histological grade, low PSA level, and negative bone and CT scans, were encouraging. Nonetheless, more than half the patients (12/20) advocated treatment as quickly as possible. Intellectual knowledge did little to attenuate feelings of fear and the desire for rapid treatment; at the most it seemed to offer only transient reassurance.

Attitudes and Misconceptions About Prostatectomy

Patients expressed their most unambiguous opinions about prostatectomy, specifically. For and against, these opinions were very polarized (Fig. 2). On the

basis of such impressions, patients *then* evaluated other, much less familiar alternatives, including external beam radiotherapy, brachytherapy, and cryotherapy.

"Surgery is Best"

One group of patients (8/20, or 40%) felt surgery was the best option because it was the most certain, the most expeditious, and the most concrete and tangible. These patients believed that "getting the tumor out" was the most definitive thing one could do, that it offered the greatest sense of finality, and that it was the standard against which all other treatment options should be judged. For these patients, physically removing a cancerous tumor was simple common sense.

The ability of surgery to provide prompt *knowledge* about the tumor was also of paramount importance, because this could help alleviate uncertainty. Prostatectomy would yield the greatest amount of information about the nature and extent of the cancer itself, such as whether it had spread outside of prostate, possibly to involve the lymph nodes. Patients believed (erroneously) that if the excised tumor was wholly confined to the prostate, treatment success would be known and cure guaranteed, alleviating considerable doubt about the future. If, on the other hand, surgery were to reveal that tumor had escaped the prostate, this information would also be invaluable because, as one patient put it, "at least I will know what I'm dealing with."

Advantages

I think it's better for me to have surgery right away. I want to see if we can't nip it in the bud right now. I wouldn't want to go through the radiation and then find out that didn't work. Then it just takes too long to do that.

...if it's confined to the prostate, and they take [the prostate] out, it's gone. And you're not going to get prostate cancer again, because it's gone.

...with radiation, you are not seeing... you are going by the PSA score afterwards – basically that would have been tough and I think surgery is just such a positive way to approach it.

If you get the surgery, then they will examine the prostate when it is out and they will know where the cancer was and that there was zero chance of it metastasizing or there was some or, but you'll have some more data.

If you have surgery you're in and out. You'll know pretty soon how you are. ...With radiation you don't know whether or not the cancer cell has jumped the boundary.

Disadvantages

I just don't trust the knife, man. I've got too many different things to worry about if I go under the knife. I mean not coming out from under the anesthesia right, or them making a mistake, or the tumor spreads... I don't want to deal with that.

...the actual surgery... they open you up and go in and cut away the prostate and the testicle or whatever and hopefully they get it all and put you back together. They actually set your guts out on the table as I understand it. ...You can get screwed up pretty bad with any surgery where you go under a general anesthetic.

...when they said surgery, I thought about going in and just doing a hack job and hacking it off. ...Well, I still envision myself having some sex life. A penile implant doesn't sound very appetizing. ...Then you go Viagra and you have to work every hour of your life to afford Viagra.

He did say you could leak [with surgery], but could you imagine wearing Depends for the rest of your life? ...I mean give me a break. I see people who have been drinking too much who wet their pants. It's not that I go around looking down at men's pants, but when you see a guy... with a big wet spot on him, then you know something's wrong.

FIGURE 2. Participant quotes regarding the advantages and disadvantages of prostatectomy.

Without exception, patients who desired surgery did not regard external beam radiotherapy, brachytherapy, and cryotherapy as attractive alternatives. An underlying theme was that these forms of therapy act upon a cancerous organ that remains hidden and unseen within the body. Furthermore, external beam radiotherapy, in particular, requires a protracted course of administration and the success and side effects of this option, as well as brachytherapy, only become evident at some indeterminate point in the future. In other words, compared with surgery, these other forms of treatment are less immediate, less visible, and more mysterious and indefinite (Fig. 2).

"Surgery is Dreadful"

In contrast to those who desired surgery, a similar-sized group of patients (11/20, or 55%) had equally strong but *negative* feelings about this option. These feelings were based on the idea that surgery (or anesthesia) is intrinsically "frightening," "drastic," and "extreme"; that death on the operating table is a real possibility; and that it is undesirable to cede complete control over one's unconscious body to physicians who may not be completely trustworthy or competent. Some patients suggested that surgery is messy or haphazard, or even rife with carnage. Some mentioned that surgery can cause a tumor to spread, or that the removal of a body part is simply

a bad idea. Some imagined, often in graphic terms, the worse possible outcomes associated with surgery (Fig. 2).

Patients who rejected prostatectomy were more likely to seriously consider alternatives. Among those who were in a position to choose, brachytherapy may have been somewhat more popular than external beam radiotherapy. Meanwhile, among patients who were ineligible for brachytherapy (e.g. because of a prior transurethral resection of the prostate or prostatic hypertrophy) external beam radiotherapy was accepted as a default option but without evident enthusiasm. No patients expressed an initial preference for cryotherapy. As primary disadvantages of external beam radiotherapy, patients cited its daily administration over six weeks and its perceived side effects. By contrast, the primary advantages of brachytherapy included convenience and minimal side effects (e.g. "it's like a prostate biopsy – a piece of cake, and you're good to go"). Two patients also mentioned that brachytherapy is "direct," a term apparently gleaned from the notion that radioactive seeds are deposited "directly" into the prostate. "Directness" was associated with greater certainty of cure, in contrast to the uncertainty of external beam radiotherapy (e.g. "let's aim at this and hope we get it").

Table 2 summarizes common knowledge deficits and mistaken ideas (misconceptions) about the risks and benefits of prostatectomy. These were prevalent

TABLE 2
Common and Influential Misconceptions About the Risks and Benefits of Prostatectomy

Misconceptions	Facts
<i>Proponents of prostatectomy:</i>	
Physically removing a cancerous tumor is the best way to guarantee cure.	Compared with prostatectomy, radiotherapy has similar, and occasionally slightly better, five-year progression free probabilities. ²⁷
Rapid surgery is most advisable to avoid the possibility that the tumor will 'spread' or suddenly metastasize ('blossom' or 'explode').	Although external beam radiotherapy may be time-consuming, the likelihood of transformation to rapidly progressive disease is remote and does not justify immediate prostatectomy. ²⁸
Surgery abolishes uncertainty if the postsurgical evaluation shows that the cancer is confined to the prostate.	Possible micrometastases and local recurrence necessitate prolonged postprostatectomy PSA surveillance. ²⁹
If the tumor has spread beyond the prostate, this information also minimizes uncertainty.	Postsurgical evidence of capsular penetration or lymph-node involvement raises uncertainty about giving radiation immediately for prevention or later as salvage therapy. ³⁰
<i>Detractors of prostatectomy:</i>	
Surgery/anesthesia is very dangerous and can lead to death. Surgery is butchery.	In eligible patients, prostatectomy/anesthesia is routine, highly structured, sterile, and very safe. ³¹
Surgery is painful and involves a prolonged recovery period.	Postoperative recovery of usual daily functioning is fairly rapid, and there are effective ways of managing postoperative pain. ³¹
Unlike other options, surgery causes impotence.	Long-term potency outcomes are similar with external beam radiotherapy. ³²
Surgery (or opening the tumor to air) can cause cancer to spread.	Exposing prostate cancer to air does not cause it to spread. ³³

among a majority of proponents and detractors of prostatectomy. It was noteworthy that, following news of the diagnosis but before their first urologic consultation, about half the patients (9/20) sought information about prostate cancer on the internet. These individuals, a majority of whom were college graduates, were just as likely as other patients to manifest misunderstandings and knowledge deficits about prostatectomy.

Failure to Weigh the Numerical Risks of Death and Treatment Side Effects

All urologists reviewed with patients the Partin table probabilities for organ-confined disease, extra-capsular extension, seminal vesicle and lymph node involvement, and lack of 5-year disease progression. Only one of the interviewed patients, however, explicitly compared surgery with its alternatives by referring to these numbers. Meanwhile, none of the patients explicitly compared treatments in terms of their relative likelihood of causing side effects. Although urologists did review the major side effects associated with each form of treatment, patients recalled this information poorly and inaccurately, even among those who had previously consulted the internet.

Several patients confused radiotherapy with chemotherapy, erroneously suggesting that the most common side effect of conformal beam radiotherapy is hair loss. Some patients, apparently having difficulty keeping track of the specific side effects associated with any one form of treatment, associated

major side effects with every form of treatment without regard to their probability of occurrence. Finally, almost half the patients (9/20) minimized concerns about side effects altogether, deeming these entirely irrelevant to the decision-making process.

[Side effects] are not important compared to dying. So you know, the rest of it is immaterial. If I have to wear Depends the rest of my life, then so be it.

The Influence of Anecdote

Nineteen patients had observed or been told about the cancer experiences of others and then had used this information to make sense of their own situation. For example, one patient with localized, potentially curable disease compared his circumstances with that of a cousin whose disease was regionally advanced and hormone-refractory. These kinds of anecdotes exerted strong sway over patients' feelings about their own prostate cancer, treatment preferences, and perceived ability to tolerate particular side effects, primarily because patients viewed prostate cancer as a uniform entity, unaware of differences in prognosis based on tumor stage and grade. In the end, patients paid much more attention to anecdotes than to population-based risk information. The following patient, for example, invoked anecdote to justify his desire for prostatectomy:

Well, see what happened to my dad [who had prostate cancer], it didn't do him no good... He had the radiation and it went through his body anyway... But my brother

just had his prostate removed last year and he is reading 0/0 on his count now and that was over a year now. So I like the results he got, so I feel that's what I'll do.

Avoiding Second Opinions

In 16/20 cases, interviewed patients said they did *not* intend to seek an independent second opinion or discuss treatment with another physician. The reasons generally reflected misconceptions about the purpose of second opinions, expressions of trust or faith in the urologist, and a desire to avoid additional delay, information overload, and prolonged uncertainty. A common misconception (5/20 patients) is that second opinions are only intended to confirm the diagnosis. A majority (6/8) of patients who desired prostatectomy made clear that a second opinion was unnecessary because they simply "trusted," "had confidence in," or "felt comfortable with" the urologist. Invariably, these patients referred to their perceptions of a urologist's personal qualities, such as directness and honesty, rather than a urologist's level of skill and experience or the pros and cons of different forms of treatment. Finally, 10/20 patients felt that second opinions would increase fear and anxiety, delay therapy, or add uncertainty to an already difficult situation.

Information Seeking and Processing

Two approaches seemed to predominate when it came to managing information about prostate cancer. About half of the patients (12/22) said that they wanted doctors or significant others to tell them what they needed to know, while the remainder (10/22) said that they were actively trying to collect and digest as many facts as possible. Among the patients who were reticent to gather information some seemed dissuaded by the unpleasantness of the topic.

I don't probe people to tell me all the details... I don't think no books or nothing like that would help me as far as reading about it because... it'd probably make me feel a little bit more insecure about it.

Another patient who was motivated initially to learn about his disease became discouraged by what he perceived to be confusing and contradictory advice.

Then I talked to these other people who have prostate surgery and they said that was the way to go. I talked to a couple of other people and they told me to take some kind of herbs and stuff, but I'm not listening to that. Someone else told me to go somewhere for some kind of treatment you know. When you listen to a lot of different people it's not good. It's not good.

Meanwhile, those for whom information seeking was important often observed that the process of assimilating it was uncertain, haphazard, and confusing.

I have a stack of papers over an inch thick probably, and I got some more today. Well, they all have differing opinions so you have to kind of read through that and you kind of try to sort it out the best way you can. I get my information mostly from doctors, hospitals, family and my own reading. ...The pamphlets and stuff I've been given, or reading newspaper articles about other people, this and that. That's what I'm talking about – resources. Just hopping around.

In summary, contending with a large quantity of sometimes contradictory information and advice was a major concern of almost every patient.

Treatment Received and Posttreatment Interviews

In only 4/20 cases did a patient subsequently request or receive treatment that did not match his initial preference (see Table 1). We were able to reach 16/20 patients for follow-up interviews 6-8 months after treatment. Fourteen of these who received treatments consistent with their initial preferences invoked exactly the same justifications that they had used prior to treatment.

DISCUSSION

We carried out detailed interviews of 20 patients with localized prostate cancer while they were still contemplating treatment but before they had initiated it. We recorded salient aspects of their decision-making experiences in real time, thereby avoiding recall bias. To our knowledge, no previously-published studies have used this methodology. On the basis of thematic analysis, we elucidated three factors that exerted particularly strong influences on initial treatment preferences. The first was profound fear and uncertainty, often corresponding with a desire to receive treatment as quickly as possible. In fact, a majority of patients were uninterested in obtaining a second opinion, typically because of concerns that this would delay treatment and increase uncertainty. Also, several patients erroneously declared that the only purpose of a second opinion is to confirm a diagnosis. Second, most patients had influential misconceptions about treatment, especially prostatectomy. Their beliefs were highly polarized: one group of patients avowed that prostatectomy is the best way of guaranteeing cure while another group asserted that it is very drastic or dangerous. Finally, almost all patients relied on anecdotes—stories about other people's cancer

experiences—to make sense of their own diagnosis and treatment choices. For the most part, these stories did not accurately match patients' own clinical circumstances.

Chart reviews and follow-up interviews revealed that most patients received treatments that matched their initial preferences. In addition, at the time of their follow-up interviews most patients invoked the same flawed ideas about prostate cancer and the same rationale for treatment that they had articulated during their initial interviews 6-8 months earlier. Although we were unable to directly determine the factors that actually influenced their final treatment choices, the persistence of these ideas bolsters our concern that many patients made early and quick decisions on the basis of erroneous and incomplete information, and then never changed their minds about treatment or altered the reasons for their choices. Altogether, these findings raise doubts about the quality of the decision-making process. Although the quality of an actual treatment *decision* in localized prostate carcinoma cannot, in general, be assessed in relation to an optimal form of treatment, the quality of the decision-making *process* is compromised when decisions are precipitous, and when they are based on significant misunderstandings and a lack of relevant knowledge.

Many of the patients we interviewed seemed as interested (and sometimes more so) in eliminating fear and minimizing uncertainty over the short term as they were in realizing cure over the longer-term. Even though most patients volunteered that prostate cancer is "slow growing," this abstract knowledge did little to dispel the vividly frightening, yet unlikely prospect of prostate cancer suddenly "exploding." Patients remained anxious and wanted to proceed with treatment as quickly as possible. Fear of death was much more prominent than fear of treatment side effects—to such an extent, in fact, that almost half the patients discounted concerns about treatment side effects altogether. In comparison with the possibility of death (which was greatly exaggerated), side effects were simply irrelevant. Another source of fear, again among nearly half the patients, was lack of definitive knowledge about the nature of the tumor. These patients believed—erroneously—that surgery furnishes the greatest amount of clinically useful knowledge and allows one to know quickly and with certainty whether cure has been achieved. Among a separate group of patients, on the other hand, prostatectomy induced fear because its dangers were magnified out of proportion to its real risks. In summary, although fear is to be expected and may be necessary for motivating serious deliberation

and action, it overpowered reason in ways that were not rectified through the simple provision of accurate health information.

In the decision science literature, an early, primitive reaction to almost any personally relevant object or event is a dichotomous good-bad evaluative assessment. Such a reaction may help to winnow down large choice sets into smaller numbers of options that are more easily contemplated.³⁴ Polarized attitudes for and against surgery may exemplify this phenomenon. Patients' first and most important step in weighing treatment alternatives seemed to depend on their beliefs about the intrinsic merits and disadvantages of prostatectomy, specifically. Assessments of prostatectomy, however, were often based on powerful misconceptions (see Table 2). Misconceptions about cancer are common and often go unrecognized even though they may exert a profound effect on patient behavior.^{35,36} Although urologists (as in this study) typically present patients with factual information that, in principle, might correct their misconceptions, it is likely that patients often fail to recognize that such information is inconsistent with their preexisting beliefs. In this way, their misconceptions persist. Alternatively, they may simply choose to discount such information.³⁷

When making treatment recommendations, physicians often rely on personal opinion and anecdote more than on high-quality evidence.³⁸ It is unsurprising that patients also rely frequently on anecdotal reasoning rather than statistical information.^{39,40} In this study, the vast majority of patients reported the influence of anecdote when forming treatment preferences. In adversity, patients seek advice from other people who are known or trusted and who have lived through seemingly similar situations. This is the basis of support groups and is a key way of garnering emotional and practical assistance from others. Anecdotal information is especially important when it provides appropriate reassurance about particular forms of treatment (e.g. that most patients, in fact, do well with prostatectomy). Conversely, anecdotal information impairs decision-making quality when it leads patients to ignore treatment alternatives or make decisions based on inaccurate appraisals of their own clinical circumstances.⁴¹

In recent years, the literature on patient-centered decision-making has emphasized the importance of *informed decision-making* (IDM) and, to a somewhat lesser degree, *shared decision-making* (SDM).⁴²⁻⁴⁵ IDM in prostate cancer occurs when a patient understands the nature of the disease, the risks and benefits of various treatment alternatives, and makes a decision consistent with his values and

outcome preferences. SDM is an extension of IDM in which the clinician assumes an active role in helping the patient to clarify and express his values and preferences, proposes a form of treatment that seems to be most consistent with the patient's values and preferences, and collaborates with the patient to arrive at a mutually satisfactory treatment decision. Both IDM and SDM emphasize the centrality of communicating medical information to patients and encouraging patients to clarify their values and preferences in ways that can be represented as declarative facts. Also, IDM and SDM tend to emphasize the presentation and framing of numerical risk information in ways that patients can easily and correctly interpret.^{46,47}

This study illustrates that although attention to health information, outcome preferences, and the framing of numerical risk is necessary, it is hardly sufficient for achieving quality in patient-centered decision-making. In particular, traditional models of IDM and SDM often give short shrift to the three powerful influences on decision-making that we identified here. First, emotions such as fear and anxiety engender a profound desire for rapid treatment that is not alleviated by intellectual knowledge that prostate cancer, for example, is "slow growing." Second, influential misconceptions about cancer and treatment are commonplace and are not easily redressed by simply imparting accurate health information. Finally, there is a natural propensity to base personal decisions on anecdotal information, even when anecdotes are not germane to patients' own circumstances. In emphasizing the importance of rational decision-making, IDM and SDM approaches implicitly stress how patients "should" behave while often overlooking how they, in fact, do behave.

To address these challenges, clinicians should strive to meet patients closer to where they actually begin the decision-making process. Explicitly describing common misconceptions may allow patients to consciously recognize and correct them. Sources of patient fear can be elucidated and, where possible, reassurance can be offered. Patients can be asked to recount stories about other people that influence their attitudes and perceptions about prostate cancer, or can be connected to other individuals who have faced similar decisions in the face of comparable risk. Then, they can be helped to understand key differences between these stories and their own circumstances. Finally, the potential value of obtaining second opinions can be made clearer.

In future work, we plan to incorporate these recommendations into treatment decision-aids. Because we found that patients tended to be either passive information recipients or active information seekers,

⁴⁸ we plan to tailor decision-aid content not only to a patient's clinical characteristics but to his preferences for handling and processing information. In comparison with usual care, we expect that such a decision-aid will lead to less precipitous and more personally satisfactory decisions, fewer treatment alternatives excluded on the basis of erroneous information, greater mutability in treatment preferences over time, and an enhanced ability to critically assess the relevance of other people's experiences with prostate cancer.

Limitations

This was a cross-sectional study of a small number of patients in a single Veterans Affairs Medical Center where, compared with the general population, patients tend to have poorer health and fewer socioeconomic resources.⁴⁹ In addition, patients in this study consulted with resident rather than attending urologists. Conversely, we included an age- and educationally diverse patient sample (including college graduates) and, for the first time, carried out comprehensive interviews during the actual decision-making period as well as 6 to 8 months following the treatment. Ultimately, we believe that the decision-making themes we have identified are likely to have universal applicability.

CONCLUSIONS

Promoting patient participation in treatment decisions requires more than the provision of medical information and the elicitation and weighing of outcome preferences. The process requires greater sensitivity to the factors that, for most patients, actually influence treatment preferences. These include fear, uncertainty, misconceptions, and anecdote.

REFERENCES

1. Bill-Axelson A, Holmberg L, Ruutu M, et al. Radical prostatectomy versus watchful waiting in early prostate cancer. *N Engl J Med*. 2005;352:1977-1984.
2. Albertsen PC, Hanley JA, Fine J. 20-year outcomes following conservative management of clinically localized prostate cancer. *JAMA*. 2005;293:2095-2101.
3. Steineck G, Helgesen E, Adolfsson J, et al. Quality of life after radical prostatectomy or watchful waiting. *N Engl J Med*. 2002;347:790-796.
4. Boehmer U, Babayan RK. A pilot study to determine support during the pre-treatment phase of early prostate cancer. *Psychooncology*. 2005;14:442-449.
5. Berry DL, Ellis WJ, Woods NE, Schwien C, Mullen KH, Yang C. Treatment decision-making by men with localized prostate cancer: The influence of personal factors. *Urol Oncol*. 2003;21:93-100.

6. O'Rourke ME, Germino BB. Prostate cancer treatment decisions: A focus group exploration. *Oncol Nurs Forum*. 1998;25:97-104.
7. Denberg TD, Beaty BL, Kim FJ, Steiner JF. Marriage and ethnicity predict treatment in localized prostate carcinoma. *Cancer*. 2005;103:1819-1825.
8. Cohen H, Britten N. Who decides about prostate cancer treatment? A qualitative study. *Fam Pract*. 2003;20:724-729.
9. Boehmer U, Babayan RK. Facing erectile dysfunction due to prostate cancer treatment: Perspectives of men and their partners. *Cancer Invest*. 2004;22:840-848.
10. Holmboe ES, Concato J. Treatment decisions for localized prostate cancer: Asking men what's important. *J Gen Intern Med*. 2000;15:694-701.
11. O'Rourke ME. Narrowing the options: The process of deciding on prostate cancer treatment. *Cancer Invest*. 1999;17:349-359.
12. Feldman-Stewart D, Brundage MD, Van Manen L, Svenson O. Patient-focussed decision-making in early-stage prostate cancer: Insights from a cognitively based decision aid. *Health Expect*. 2004;7:126-141.
13. Boehmer U, Clark JA. Communication about prostate cancer between men and their wives. *J Fam Pract*. 2001;50:226-231.
14. Boehmer U, Clark JA. Married couples' perspectives on prostate cancer diagnosis and treatment decision-making. *Psychooncology*. 2001;10:147-155.
15. Bokhour BG, Clark JA, Inui TS, Silliman RA, Talcott JA. Sexuality after treatment for early prostate cancer: Exploring the meanings of "erectile dysfunction". *J Gen Intern Med*. 2001;16:649-655.
16. Chapman GB, Elstein AS, Kuzel TM, Nadler RB, Sharifi R, Bennett CL. A multi-attribute model of prostate cancer patient's preferences for health states. *Qual Life Res*. 1999;8:171-180.
17. Mazur DJ, Hickam DH. Patient preferences for management of localized prostate cancer. *West J Med*. 1996;165:26-30.
18. Mazur DJ, Hickam DH, Mazur MD. How patients' preferences for risk information influence treatment choice in a case of high risk and high therapeutic uncertainty: Asymptomatic localized prostate cancer. *Med Decis Making*. 1999;19:394-398.
19. Steginga SK, Occhipinti S, Gardiner RA, Yaxley J, Heathcote P. Making decisions about treatment for localized prostate cancer. *BJU Int*. 2002;89:255-260.
20. Alexander T. One man's tough choices on prostate cancer. *Fortune*. 1993;128:86-88,90,92.
21. Grove A. Taking on Prostate Cancer. *Fortune*. 1996;133:54-72.
22. Wegner RE. Deciding on radical prostatectomy: A patient's perspective. *Semin Urol Oncol*. 2000;18:192-199.
23. Seale C, Gobo G, Gubrium J, Silverman D. Qualitative Research Practice. London: Sage; 2004.
24. Partin AW, Kattan MW, Subong EN, et al. Combination of prostate-specific antigen, clinical stage, and Gleason score to predict pathological stage of localized prostate cancer. A multi-institutional update. *JAMA*. 1997;277:1445-1451.
25. AstraZeneca Pharmaceuticals LP. Prostate Cancer: What it is and How it is Treated. A Booklet for Patients. Wilmington, DE; 2002. Available at www.PROSTATEinfo.com.
26. Strauss A, Corbin J. Basics of Qualitative Research: Grounded Theory Procedures and Techniques. Newbury Park, CA: Sage; 1990.
27. Shipley WU, Thames HD, Sandler HM, et al. Radiation therapy for clinically localized prostate cancer: A multi-institutional pooled analysis. *JAMA*. 1999;281:1598-1604.
28. British Association of Urological Surgeons. Guidelines on the Management of Prostate Cancer. UK: Royal College of Radiologists; 1999.
29. Moul JW. Prostate specific antigen only progression of prostate cancer. *J Urol*. 2000;163:1632-1642.
30. Bolla M, van Poppel H, Collette L, van Cangh P, Vekemans K, Da Pozzo L, et al. Postoperative radiotherapy after radical prostatectomy: A randomised controlled trial (EORTC trial 22911). *Lancet*. 2005;366:572-578.
31. Chang SS, Cole E, Smith JA Jr, Baumgartner R, Wells N, Cookson MS. Safely reducing length of stay after open radical retropubic prostatectomy under the guidance of a clinical care pathway. *Cancer*. 2005;104:747-751.
32. Potosky AL, Davis WW, Hoffman RM, et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: The prostate cancer outcomes study. *J Natl Cancer Inst*. 2004;96:1358-1367.
33. Margolis ML, Christie JD, Silvestri GA, Kaiser L, Santiago S, Hansen-Flaschen J. Racial differences pertaining to a belief about lung cancer surgery: Results of a multicenter survey. *Ann Intern Med*. 2003;139:558-563.
34. Hastie R. Problems for judgment and decision making. *Annu Rev Psychol*. 2001;52:653-683.
35. Denberg TD, Wong S, Beattie A. Women's misconceptions about cancer screening: Implications for informed decision-making. *Patient Educ Couns*. 2005;57:280-285.
36. Gansler T, Henley SJ, Stein K, Nehl EJ, Smigal C, Slaughter E. Sociodemographic determinants of cancer treatment health literacy. *Cancer*. 2006;106:726,727.
37. Farrell MH, Murphy MA, Schneider CE. How underlying patient beliefs can affect physician-patient communication about prostate-specific antigen testing. *Eff Clin Pract*. 2002;5:120-129.
38. Landon BE, Reschovsky J, Reed M, Blumenthal D. Personal, organizational, and market level influences on physicians' practice patterns: Results of a national survey of primary care physicians. *Med Care*. 2001;39:889-905.
39. Borgida E, Nisbett R. The differential impact of abstract versus concrete information on decisions. *J Appl Soc Psychol*. 1977;7:258-271.
40. Fagerlin A, Wang C, Ubel PA. Reducing the influence of anecdotal reasoning on people's health care decisions: Is a picture worth a thousand statistics? *Med Decis Making*. 2005;25:398-405.
41. Tversky A, Kahneman D. Evidential impact of base rates. In: Kahneman D, Slovic P, Tversky A, eds. *Judgment Under Uncertainty: Heuristics and Biases*. Cambridge University Press, 1982:153-160. (QA for the place of publisher).
42. Barry MJ. Involving patients in medical decisions: How can physicians do better? *JAMA*. 1999;282:2356,2357.
43. Braddock CH III, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: Time to get back to basics. *JAMA*. 1999;282:2313-2320.
44. Holmes-Rovner M, Valade D, Orlowski C, Draus C, Nabozny-Valerio B, Keiser S. Implementing shared decision-making in routine practice: Barriers and opportunities. *Health Expect*. 2000;3:182-191.

45. O'Connor AM, Legare F, Stacey D. Risk communication in practice: The contribution of decision aids. *BMJ*. 2003;327:736-740.
46. Edwards A, Elwyn G, Mulley A. Explaining risks: Turning numerical data into meaningful pictures. *BMJ*. 2002;324:827-830.
47. Alaszewski A, Horlick-Jones T. How can doctors communicate information about risk more effectively? *BMJ*. 2003;327:728-731.
48. Miller S. Monitoring and blunting in the face of threat: Implications for adaptation and health. In: Montada L, Filipp S, Lerner M, eds. *Life Crises and Experiences of Loss in Adulthood*. Englewood Cliffs, NJ: Erlbaum; 1991:255-273.
49. Agha Z, Lofgren RP, VanRuiswyk JV, Layde PM. Are patients at veterans affairs medical centers sicker? A comparative analysis of health status and medical resource use. *Arch Intern Med*. 2000;160:3252-3257.

Prostate Cancer Testing following a Negative Prostate Biopsy: Over Testing the Elderly

Richard M. Hoffman, MD, MPH^{1,2}, Thomas Denberg, MD, PhD³, William C. Hunt, MS², and Ann S. Hamilton, PhD⁴

¹Department of Medicine, New Mexico VA Health Care System, 111GIM 1501 San Pedro Drive SE, Albuquerque, New Mexico 87108, USA;

²University of New Mexico Cancer Research and Treatment Center, Albuquerque, New Mexico, USA; ³Division of General Internal Medicine, Department of Medicine, University of Colorado at Denver and Health Sciences Center, Denver, Colorado, USA; ⁴Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, California, USA.

BACKGROUND: Screening elderly men for prostate cancer is not recommended because definitive treatments are unlikely to extend life expectancy.

OBJECTIVE: Describe clinical outcomes after a negative prostate biopsy in a population-based cohort of men ages 65 and older.

DESIGN: Retrospective cohort study.

PARTICIPANTS: 9,410 Medicare-eligible men who underwent a prostate biopsy in Los Angeles or New Mexico in 1992.

MEASUREMENTS: We used Medicare and SEER databases to identify a cohort with an initial negative biopsy ($n=7,119$) and to ascertain survival, subsequent PSA testing, prostate biopsies, and prostate cancer detection and treatment through 1997.

RESULTS: The overall 5-year survival was 79.4% (95% CI 78.4–80.3), but only 74.6% (72.4–76.7) for men ages 75–79 at the time of the initial negative biopsy and 55.0% (51.9–57.9) for men ages 80+. During a median 4.5 years follow-up, a cumulative 75.0% (73.9–76.1) of the cohort underwent PSA testing. Among men ages 75–79 and 80+, the cumulative proportions that underwent PSA testing were 75.4% (73.0–77.8) and 74.3% (71.1–77.5), respectively. Additionally, 29.1% (26.7–31.6) of men ages 75–79 and 20.1% (17.6–23.1) of men ages 80+ underwent repeat prostate biopsy, and 10.9% (9.4–12.7) and 8.3% (6.6–10.4), respectively, were diagnosed with cancer. Among men ages 75+ with localized cancers, approximately 34% received definitive treatment.

CONCLUSIONS: High proportions of men ages 75+ underwent PSA testing and repeat prostate biopsies after an initial negative prostate biopsy. Given the known harms and uncertain benefits for finding and treating localized cancer in elderly men, most continued PSA testing after a negative biopsy is potentially inappropriate.

KEY WORDS: prostate-specific antigen; prostate cancer screening; prostate cancer treatment; elderly.

DOI: 10.1007/s11606-007-0248-7

© 2007 Society of General Internal Medicine 2007;22:1139–1143

BACKGROUND

The benefits of prostate cancer screening and the optimal treatment for localized disease are uncertain. Prostate-specific antigen (PSA) testing is controversial because the efficacy of screening has yet to be confirmed in randomized controlled trials.¹ Testing elderly men is considered problematic even by the professional societies whose guidelines support screening. The American Urologic Association, American Cancer Society, and the National Comprehensive Cancer Network all recommend against screening men with less than a 10-year life expectancy.^{2–4} Based on actuarial data, screening should stop at age 75 years for men in average health. Observational studies have shown that older men with localized cancers—the target of screening efforts—have relatively high rates of disease-specific survival even without treatment.^{5,6} Claims data have consistently shown that older men also have the highest rates of treatment morbidity and mortality, particularly with radical prostatectomy.^{7,8}

Despite these concerns, survey, claims, and laboratory data show considerable PSA testing occurring in men ages 75 years and older.^{9–13} However, these data sources cannot always distinguish screening in asymptomatic men from diagnostic testing in men with findings suspicious for cancer. One cohort for whom further PSA testing should generally be considered inappropriate is comprised of men who have undergone a negative prostate biopsy at age 75 years or older. Although prostate needle biopsy is an imperfect gold standard,^{14,15} a negative biopsy substantially reduces the likelihood of subsequently detecting cancer.¹⁶ In addition, most cancers found on repeat biopsies are early stage.¹⁶ Given that the estimated mean lead time for PSA testing is at least 5 to 10 years,^{17,18} the majority of any subsequently detected early-stage cancers would not have been found in the absence of PSA testing. Furthermore, the single randomized trial that demonstrated efficacy for aggressively treating localized cancers found a survival advantage only for men age 65 years and younger at the time of diagnosis.¹⁹

This work was presented in part at the Annual National Meeting of the Society for General Internal Medicine, Los Angeles, California, May 2006.

Received November 16, 2006

Revised April 17, 2007

Accepted May 3, 2007

Published online June 7, 2007

We linked Medicare and Surveillance Epidemiology and End Results (SEER) data files to describe clinical outcomes after a negative prostate biopsy—subsequent PSA testing, repeat prostate biopsies, subsequent cancer diagnoses, and treatment for early-stage cancer—in a population-based cohort of older men.

METHODS

Cohort Assembly. We retrospectively assembled a study cohort using the 1992 Medicare Denominator and Physician Part B claims files to identify subjects residing in either the state of New Mexico or Los Angeles County who underwent prostate biopsy from January 1, 1992 through December 31, 1992. We identified prostate biopsies or ultrasound-guided biopsies by Physicians Current Procedure Terminology (CPT) Fourth Edition codes 55700, 55705, 76942, and 76943.

We linked the Medicare claims files for men who underwent prostate biopsy in 1992 with the New Mexico and Los Angeles County SEER tumor registry databases. Linkages were based on either (1) an exact match of the social security number and at least 6 of 8 digits for date of birth or (2) an exact match on date of birth and at least 8 digits of the social security number. We used the linkage to exclude men with prevalent prostate cancers before the initial 1992 (index) prostate biopsy and to identify cases of prostate cancer detected by the index biopsy as well as those detected by a subsequent biopsy. A subject was considered to have undergone a negative index biopsy if we found no cancer match in the 8 weeks after the index biopsy. For cancers identified through the linkage, we obtained additional information on tumor stage, grade, and treatment. Stage was classified as localized (confined to the prostate), regional (extension beyond the prostate capsule including regional lymph nodes), and distant (metastasis). Stage was based on clinical findings unless the patient underwent radical prostatectomy, which provides pathologic staging. The SEER registries classify tumor grade based on level of cellular differentiation. Grade I is well differentiated (corresponding to Gleason scores 2–4), Grade II is moderately well differentiated (Gleason 5–7), and Grade III is poorly differentiated (Gleason 8–10). The SEER registries report initial treatment (particularly radical prostatectomy or radiation therapy) received or planned within 4 months of diagnosis. Reliable data on androgen deprivation treatment are not routinely available.

Follow-up. We used Medicare claims data to follow the negative biopsy cohort through December 31, 1997, using CPT and ICD-9 codes to identify subsequent prostate-specific antigen testing (CPT code 84153) and prostate biopsies (CPT codes 55700, 55705, 76942, and 76943; ICD-9 code 60.1). We linked the cohort to the New Mexico and Los Angeles County tumor registry databases to identify prostate cancers found subsequent to the negative index biopsy and to obtain information on cancer stage, grade, and treatment. If a cancer was diagnosed without a preceding CPT code for a prostate biopsy, we counted the patient as having had a biopsy unless we found a preceding code for transurethral resection of the prostate (52601, 52612, 52614, 52620, 52630) or if prostate

cancer was diagnosed only at the time of death. We used Medicare vital status files to determine date of death.

Data Analysis. We used Kaplan–Meier analyses to estimate the cumulative proportions of patients undergoing PSA testing, undergoing repeat prostate biopsy, and receiving a prostate cancer diagnosis through the end of the study period. We used the log-rank test to test for differences in cumulative proportions of the clinical outcomes across age groups (65–69, 70–74, 75–79, 80+) at the time of the index biopsy. We also estimated rates of PSA testing, prostate biopsy, and cancer detection based on the number of events over person years at risk. Subjects were censored at the time of death, cancer diagnosis, or end of study (December 31, 1997) for analyses of PSA testing and repeat prostate biopsy. They were also censored for cancer detection analyses when they moved away from their initial geographic area (based on Medicare denominator files) because we could no longer obtain tumor registry data. We used chi-square tests to compare demographics between patients with cancer diagnosed on the initial biopsy and those who were diagnosed on a subsequent biopsy and to compare cancer treatments across age groups. We classified treatment as definitive if the subject underwent radical prostatectomy or radiation therapy.

RESULTS

We identified 10,059 men from the Medicare file who underwent an index prostate biopsy in 1992 either in Los Angeles County (8,197) or New Mexico (1,862). We excluded 649 men with a prevalent prostate cancer before the index biopsy. Overall, 2,291 of 9,410 (24.3%) men were diagnosed with prostate cancer with the index biopsy; cancer detection was significantly associated with older age and location (Table 1).

The follow-up study cohort was comprised of the 7,119 men with an initial negative biopsy. By December 31, 1997, the cohort had accumulated 31,938 person years of follow-up, an average of 4.5 years per person. The overall 5-year survival was 79.4% (95% CI 78.4–80.3%). However, 5-year survival was only 74.6% (95% CI 72.4–76.7%) for men ages 75 to 79 years at the time of initial biopsy and 55.0% (95% CI 51.9–57.9%) for those age 80 years and older. Meanwhile, 5-year survival for men ages 65 to 69 years was 89.9% (95% CI 88.6–91.1) and 84.0% (95% CI 82.4–85.4%) for men ages 70 to 74 years. The PSA testing rate was 74.1/100 person years (95% CI 73.2–75.1/100 person years). During follow-up, the cohort underwent 23,671 PSA tests with a cumulative testing proportion of 75.0% (95% CI 73.9–76.1%) (Table 2, Fig. 1). Table 2 also shows the cumulative proportion of men undergoing PSA testing by age group at the time of the initial biopsy. We found no significant age-specific differences in PSA testing. The majority of PSA tests were not linked to a provider type.

Overall, the cohort underwent 3,007 repeat biopsies, with a biopsy rate of 9.4/100 person years (95% CI 8.9–10.0/100 person years). The number of repeat biopsies per person ranged from 1 to 7, with a median of 1 (data not shown). The cumulative proportion of men undergoing repeat biopsy was 32.2% (95% CI 31.1–33.4%) (Table 2, Fig. 1). The cumulative proportion undergoing biopsy was significantly lower for older men compared to younger men, although 29.1% of men ages

Table 1. Baseline Characteristics of Men at the Time of 1992 Index Prostate Biopsy

	Positive biopsy		Negative biopsy		Cancer detection (%)
	N	Column %	N	Column %	
Total	2,291	100.0	7,119	100.0	24.3
Age at biopsy*					
65–69	549	24.0	2,151	30.2	20.3
70–74	748	32.6	2,339	32.9	24.2
75–79	585	25.5	1,573	22.1	27.1
80+	409	17.9	1,056	14.9	27.9
Location†					
Los Angeles	1,757	76.7	5,954	83.6	22.8
New Mexico	534	23.3	1,165	16.4	31.4

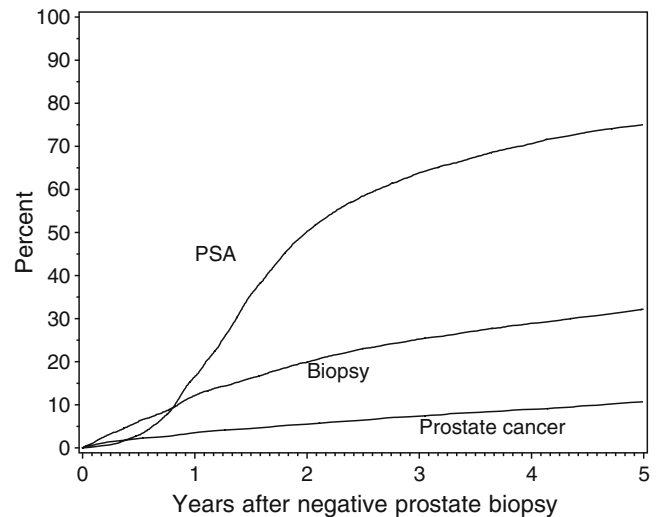
*P value < .001

†P value < .0001

75 to 79 years and 20.1% of men ages 80 years and older underwent a repeat biopsy (Table 2). Additionally, 16% of the repeat biopsies in men ages 70 to 74 years at the time of the index biopsy occurred when the subject was age 75 years or older. The overall proportion of biopsies to PSA tests was lower for men ages 75 years and older (10.0%) than for younger men (14.6%), $P < .0001$.

Prostate cancer was detected in 741 subjects by the end of the study period with a cancer detection rate of 2.3/100 person years (95% CI 2.2–2.5/100 person years). The cumulative proportion of men diagnosed with cancer was 10.7% (95% CI 9.9–11.5%) (Table 2, Fig. 1). Table 2 also shows the cumulative proportion of cancer detection by age group at the time of the initial biopsy. The cumulative proportions of cancer detection were similar for the 3 youngest age groups, but slightly lower for men ages 80 years and older.

The proportion of men receiving definitive treatment for localized prostate cancer was significantly lower for men ages 75 years and older at the time of the negative index biopsy, although 42.7% of men ages 75 to 79 years received radical

**Fig. 1. Cumulative proportions of PSA testing, repeat biopsy, and cancer diagnosis following initial negative biopsy.**

prostatectomy or radiation therapy (Table 3). We also re-analyzed the data after reclassifying the 292 men with regional stage cancers who underwent radical prostatectomy as having a clinically localized cancer at diagnosis. We did this because the summary SEER stage reflects pathologic staging in men who underwent radical prostatectomy—which could lead to underestimating the number of subjects with clinically localized cancer. Even with the stage reclassification, the associations between age group at diagnosis and treatment received were unchanged (data not shown).

DISCUSSION

The 5-year overall cumulative proportion of PSA testing in elderly men ages 75 years and older after a negative prostate biopsy was approximately 75%, very similar to the testing rate in younger men. However, the 5-year survival was much lower for the elderly men. Nonetheless, as a result of this PSA testing, 29.1% of men ages 75 to 79 years and 20.1% of men ages 80 years and older underwent at least 1 subsequent prostate biopsy. Cancer was detected in 10.9% of men ages 75 to 79 years and in 8.3% of those ages 80 years and older; nearly 34% of the elderly men diagnosed with early-stage cancer received definitive treatment.

Table 2. Cumulative Proportions of Men Undergoing PSA Testing, Repeat Biopsy, and Cancer Detection within 5 Years After Negative Index Prostate Biopsy, Overall and Stratified by Age at Index Biopsy

Age at index biopsy	PSA testing % (95% CI)	Repeat biopsy % (95% CI)	Cancer detection % (95% CI)
All ages	75.0 (73.9, 76.1)	32.2 (31.1, 33.4)	10.7 (9.9, 11.5)
65–69 (reference)	74.6 (72.6, 76.5)	36.0 (34.0, 38.2)	10.2 (9.0, 11.6)
70–74	75.4 (73.4, 77.2)	35.1 (33.1, 37.1)	11.8 (10.5, 13.2)
75–79	75.4 (73.0, 77.8)	29.1 (26.7, 31.6) *	10.9 (9.4, 12.7)
80+	74.3 (71.1, 77.5)	20.1 (17.6, 23.1) *	8.3 (6.6, 10.4) †

*P < .0001 vs reference

†P = .05 vs reference

Table 3. Treatment Received for Localized Prostate Cancer Detected by Subsequent Biopsy Stratified by Age at Negative Index Biopsy

Age at negative index biopsy	N	Definitive treatment* % (95% CI)	Radical prostatectomy % (95% CI)
65–69 (reference)	177	75.7 (69.2, 82.1)	55.9 (48.5, 63.4)
70–74	208	66.4 (58.9, 72.6) †	31.7 (11.2, 21.9) ‡
75–79	117	42.7 (34.1, 52.7) ‡	17.1 (10.9, 25.5) ‡
80+	45	11.1 (3.7, 24.1) ‡	2.2 (0.1, 11.8) ‡

*Radical prostatectomy or radiation therapy

†P < 0.03 vs reference

‡P < 0.0001 vs reference

The high proportion of men older than age 75 years who underwent PSA testing is consistent with testing rates reported by the 2000 National Health Interview Survey^{9,11} and the 1999 to 2002 National Ambulatory Medical Care Survey.¹⁰ Among men ages 75 years and older, over 30% reported PSA testing within the past year, including a substantial proportion who self-described themselves as being in fair or poor health.¹⁰ Walter and colleagues determined that 51% of veterans over age 75 years underwent PSA screening tests in 2003, with relatively similar within age-group testing rates regardless of health status as measured by the Charlson-Deyo Comorbidity Index.¹³ These PSA testing practices are concerning. Efforts to find cancers in men with less than a 10-year life expectancy by screening are not supported by any guidelines because elderly men are not expected to live long enough to gain a survival benefit from aggressively treating an early-stage cancer.¹ However, PSA testing in elderly patients could appropriately be driven by lower urinary tract or systemic symptoms because diagnosing clinically-advanced prostate cancer could alter treatment strategies.

Our Medicare cohort of men ages 75 years and older all had undergone a negative biopsy. Guidelines do suggest repeating a prostate biopsy when the pathology is suspicious for cancer without necessarily first repeating a PSA.² Accordingly, we found that a higher cumulative proportion of men underwent biopsy than underwent PSA tests in the 6 months after the index negative biopsy (Fig. 1). Continued surveillance PSA testing could reflect clinical suspicion (based on PSA level and/or digital rectal examination findings) that a cancer was missed, and a rising or persistently elevated PSA might be an indication for a repeat biopsy. However, the chances that the index biopsy missed an advanced-stage tumor are small.¹⁶ The relatively indolent course of early-stage prostate cancer in the elderly^{5,6}—and the lack of evidence supporting aggressive treatment for the elderly¹⁹—suggests that continued PSA testing would not be expected to increase survival. In addition, it is unlikely that new urinary tract or systemic symptoms—which could prompt diagnostic PSA testing—occurring within 5 years of a negative biopsy could be attributed to prostate cancer.

A limitation of the study is that we do not know the indication for PSA testing. However, based on previous reports characterizing PSA testing in the elderly,^{9–13} cancer detection after a negative biopsy,¹⁶ and the natural history of prostate cancer,^{5,6} we believe that most subsequent PSA testing in our cohort was potentially inappropriate, whether it was intended for screening, surveillance, or diagnosis.

The majority of PSA testing after the initial negative biopsy was not linked to a provider type. However, based on previous national survey data, we suspect that primary care providers likely drive the high rate of PSA testing in older men.^{20–22} According to these studies, primary care providers are much more aggressive in ordering PSA testing than urologists and have greater expectations for the benefits of definitive treatment than is warranted by the evidence. Although the cumulative proportion of PSA testing approached 75% in the older age groups, a relatively smaller proportion underwent re-biopsy. Given that the proportion of elevated PSA levels was probably higher in the older age groups than in the younger age groups,²³ these findings are consistent with a survey report that urologists are less inclined than primary care providers to routinely recommend biopsies for older men with an elevated PSA.²⁰

When cancers were detected in elderly men, about one-third of them were definitively treated, with just 13% undergoing radical prostatectomy. This conservative management is reasonable given the higher complication risk for older men after radical prostatectomy^{7,8,24} and the limited treatment benefit for older men.^{19,25} However, this raises a question about the purpose of testing men ages 75 and older for prostate cancer. The goal of screening is to identify early-stage cancers because they are potentially curable with definitive treatment. Finding, but not definitively treating—or needing to definitively treat—early-stage cancers in elderly men undermines the purpose of screening. Such men face the psychological burden of a cancer diagnosis without any expectation or need for a cure. Although elderly men may receive androgen deprivation therapy, these treatments can impair quality of life²⁶ and potentially cause diseases²⁷ with no evidence that they prolong life for men with early-stage disease. The quandary surrounding treatment decisions for elderly men with early-stage cancers can be avoided by not screening them in the first place.

Our study had some potential limitations. Although we found that older men with clinically localized cancers were less likely than younger men to receive aggressive treatment, we were unable to adjust the comparisons for comorbidities or know whether patients received androgen deprivation therapy. However, if comorbid conditions prevented men from receiving definitive treatments, these conditions should potentially also have limited efforts to detect cancer. Possibly, our results are now less relevant given temporal changes in prostate cancer diagnosis and treatment. Surveillance Epidemiology and End Results (SEER) data have shown declining prostate cancer incidence rates for older men. For example, the age-specific incidence rate was 1118.5 per 100,000 for men ages 75 to 79 years during the period 1993 to 1997.²⁸ The most recent SEER data (2000 to 2003) reported a rate of only 1,032.3 per 100,000.²⁹ Even larger declines in incidence rates were reported for men ages 80 to 84 years, from 1018.6 to 842.4 per 100,000. However, multiple data sources still document high testing rates in elderly men.^{9–13} Although recent data suggest that fewer men over age 70 years receive radical prostatectomy, the proportion being treated with brachytherapy has increased and the overall treatment rates are relatively stable.⁷

We may have underestimated cancer detection if we missed matching Medicare and tumor registry data owing to errors in personal identifiers. We may have incorrectly included men with a prevalent cancer in our cohort if they had not been diagnosed in Los Angeles or New Mexico. This would primarily result in misclassifying surveillance PSA testing as diagnostic testing, although it should not substantially alter our estimates for biopsies. Finally, our results may not be generalizable to geographic locations other than Los Angeles or New Mexico.

We found a high rate of PSA testing in a Medicare cohort of elderly men after a negative prostate biopsy. Other studies have also reported that PSA testing is common among older men.^{9–13} Unlike these studies, we were also able to provide data on the clinical outcomes associated with PSA testing. We found that the problem of potentially inappropriate PSA testing in men ages 75 years and older is compounded by relatively high rates of repeat biopsies and aggressive therapy for men with early-stage cancer despite their decreased life expectancy, particularly for those older than age 80 years. Given that the benefit of finding and treating prostate cancer in elderly men is uncertain, primary care providers have an important respon-

sibility to avoid recommending and/or ordering unnecessary PSA tests. Older patients need to understand that continued efforts to find prostate cancer are unlikely to improve survival while potentially subjecting them to the psychological harms of diagnosis and the physical and financial burdens of treatment.

Acknowledgements: This project was supported by the National Cancer Institute: N01-PC-85063-20. This project was also supported in part by National Cancer Institute Contract N01-PC-35138 for the New Mexico Tumor Registry and Contract N01-PC-67010 for the Los Angeles County Tumor Registry.

This project was also supported by the New Mexico VA Health Care System and the University of New Mexico Cancer Research and Treatment Center.

The collection of the Los Angeles cancer incidence data used in this study was supported by the California Department of Health Services as part of the statewide cancer reporting program mandated by California Health and Safety Code Section 103885; the National Cancer Institutes Surveillance, Epidemiology and End Results Program under contract N01-PC-35139 awarded to the Northern California Cancer Center, contract N01-PC-35139 awarded to the University of Southern California, and contract N02-PC-15105 awarded to the Public Health Institute; and the Centers for Disease Control and Preventions National Program of Cancer Registries, under agreement #U55/CCR921930-02 awarded to the Public Health Institute. The ideas and opinions expressed herein are those of the author(s) and endorsement by the State of California, Department of Health Services, the National Cancer Institute, and the Centers for Disease Control and Prevention or their contractors and subcontractors is not intended nor should be inferred.

The authors thank Arnold Potosky, PhD, for his helpful comments on an earlier manuscript draft, and Meg Adams-Cameron, MPH, for her help with grant preparation and data acquisition.

Conflicts of Interest: None disclosed.

Corresponding Author: Richard M. Hoffman, MD, MPH; New Mexico VA Health Care System, Albuquerque, New Mexico, USA (e-mail: rhoffman@unm.edu).

REFERENCES

- Harris R, Lohr KN. Screening for prostate cancer: an update of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2002;137(11):917-29.
- National Comprehensive Cancer Network. Prostate Cancer Early Detection. Clinical Practice Guidelines in Oncology. Version 1.2005 ed., vol. 2005; 2005.
- Smith RA, Cokkinides V, von Eschenbach AC, et al. American Cancer Society guidelines for the early detection of cancer. *CA Cancer J Clin*. 2002;52(1):8-22.
- Carroll P, Coley C, McLeod D, et al. Prostate-specific antigen best practice policy. Part II. prostate cancer staging and post-treatment follow-up. *Urology*. 2001;57(2):225-9.
- Albertsen PC, Hanley JA, Fine J. 20-year outcomes following conservative management of clinically localized prostate cancer. *JAMA*. 2005;293(17):2095-101.
- Johansson JE, Andren O, Andersson SO, et al. Natural history of early, localized prostate cancer. *JAMA*. 2004;291(22):2713-9.
- Bubolz T, Wasson JH, Lu-Yao G, Barry MJ. Treatments for prostate cancer in older men: 1984-1997. *Urology*. 2001;58(6):977-82.
- Lu-Yao GL, Albertsen P, Warren J, Yao SL. Effect of age and surgical approach on complications and short-term mortality after radical prostatectomy—a population-based study. *Urology*. 1999;54(2):301-7.
- Ross LE, Coates RJ, Breen N, Uhler RJ, Potosky AL, Blackman D. Prostate-specific antigen test use reported in the 2000 National Health Interview Survey. *Prev Med*. 2004;38(6):732-44.
- Scales CD, Jr., Curtis LH, Norris RD, Schulman KA, Albala DM, Moul JW. Prostate specific antigen testing in men older than 75 years in the United States. *J Urol*. 2006;176(2):511-4.
- Lu-Yao G, Stukel TA, Yao SL. Prostate-specific antigen screening in elderly men. *J Natl Cancer Inst*. 2003;95(23):1792-7.
- Richter F, Dudley AW, Jr., Irwin RJ, Jr., Sadeghi-Nejad H. Are we ordering too many PSA tests? Prostate cancer diagnosis and PSA screening patterns for a single Veterans Affairs Medical Center. *J Cancer Educ*. 2001;16(1):38-41.
- Walter LC, Bertenthal D, Lindquist K, Konety BR. PSA screening among elderly men with limited life expectancies. *JAMA*. 2006;296(19):2336-42.
- Stroubakis N, Cookson MS, Reuter VE, Fair WR. Clinical significance of repeat sextant biopsies in prostate cancer patients. *Urology*. 1997;49(3A Suppl):113-8.
- Djavan B, Zlotta A, Remzi M, et al. Optimal predictors of prostate cancer on repeat prostate biopsy: a prospective study of 1,051 men. *J Urol*. 2000;163(4):1144-8; discussion 1148-9.
- Roobol MJ, Van der Crujisen IW, Schroder FH. No reason for immediate repeat sextant biopsy after negative initial sextant biopsy in men with PSA level of 4.0 ng/mL or greater (ERSPC, Rotterdam). *Urology*. 2004;63(5):892-7; discussion 897-9.
- Draisma G, Boer R, Otto SJ, et al. Lead times and overdetected due to prostate-specific antigen screening: estimates from the European Randomized Study of Screening for Prostate Cancer. *J Natl Cancer Inst*. 2003;95(12):868-78.
- Gann PH, Hennekens CH, Stampfer MJ. A prospective evaluation of plasma prostate-specific antigen for detection of prostatic cancer. *JAMA*. 1995;273(4):289-94.
- Bill-Axelsson A, Holmberg L, Ruutu M, et al. Radical prostatectomy versus watchful waiting in early prostate cancer. *N Engl J Med*. 2005;352(19):1977-84.
- Fowler FJ, Jr., Bin L, Collins MM, et al. Prostate cancer screening and beliefs about treatment efficacy: a national survey of primary care physicians and urologists. *Am J Med*. 1998;104(6):526-32.
- McNaughton Collins M, Stafford RS, Barry MJ. Age-specific patterns of prostate-specific antigen testing among primary care physician visits. *J Fam Pract*. 2000;49(2):169-72.
- Han PK, Coates RJ, Uhler RJ, Breen N. Decision making in prostate-specific antigen screening national health interview survey, 2000. *Am J Prev Med*. 2006;30(5):394-404.
- Oesterling JE, Jacobsen SJ, Chute CG, et al. Serum prostate-specific antigen in a community-based population of healthy men. Establishment of age-specific reference ranges. *JAMA*. 1993;270(7):860-4.
- Wilt TJ, Cowper DC, Gammack JK, Going DR, Nugent S, Borowsky SJ. An evaluation of radical prostatectomy at Veterans Affairs Medical Centers: time trends and geographic variation in utilization and outcomes. *Med Care*. 1999;37(10):1046-56.
- Ross KS, Guess HA, Carter HB. Estimation of treatment benefits when PSA screening for prostate cancer is discontinued at different ages. *Urology*. 2005;66(5):1038-42.
- Potosky AL, Reeve BB, Clegg LX, et al. Quality of life following localized prostate cancer treated initially with androgen deprivation therapy or no therapy. *J Natl Cancer Inst*. 2002;94(6):430-7.
- Keating NL, O'Malley AJ, Smith MR. Diabetes and cardiovascular disease during androgen deprivation therapy for prostate cancer. *J Clin Oncol*. 2006;24(27):4448-56.
- Ries LAG, Eisner MP, Kosary CL, et al. (National Cancer Institute). SEER Cancer Statistics Review, 1973-1997; 2000.
- Ries LAG, Harkins D, Krapcho M, et al. (National Cancer Institute). SEER Cancer Statistics Review, 1975-2003; 2006.

Trends and predictors of aggressive therapy for clinical locally advanced prostate carcinoma

THOMAS D. DENBERG, L. MICHAEL GLODÉ, JOHN F. STEINER, E. DAVID CRAWFORD and RICHARD M. HOFFMAN*

University of Colorado at Denver and Health Sciences Center, Denver, CO, and the *University of New Mexico and New Mexico Veterans Affairs Health Care System, NM, USA

Accepted for publication 16 March 2006

OBJECTIVE

To determine the patterns and predictors of aggressive local therapies for patients with clinically advanced (cT3) prostate carcinoma, as the USA National Cancer Institute considers external beam radiotherapy (EBRT) to be the most appropriate treatment for these patients, and currently there is less evidence supporting the use of radical prostatectomy (RP).

PATIENTS AND METHODS

We used the Surveillance, Epidemiology and End Results (SEER) cancer registries to identify patients diagnosed with cT3 disease between 1995 and 2001. Sociodemographic and clinical data included patient age, race/ethnicity, marital status, SEER registry, year of

diagnosis, tumour stage and grade, and treatment. Multivariate logistic regression was used to identify significant predictors of receiving (i) RP vs EBRT, (ii) any aggressive local treatment (RP or EBRT) or no treatment.

RESULTS

Between 1995 and 2001, the proportion of men receiving aggressive local therapy for cT3 disease increased by 11% (58.4% to 69.4%), with a 20% increase in EBRT (40.3% to 60.2%) but a decline by half in RP (18.1% to 9.3%). Younger age was the strongest predictor of receiving RP rather than EBRT, and younger age with being married being a predictor of receiving aggressive local therapy (adjusted relative risk for marriage 1.33, 95% confidence interval 1.18–1.87). Black men were significantly less likely than non-

Hispanic white men to receive aggressive therapy, with a relative risk of 0.56 (0.45–0.69).

CONCLUSION

By 2001, 70% of patients with cT3 disease were receiving aggressive local therapy, with EBRT 6.5 times more common than RP. Clinical trials are needed to rigorously assess the effects of different local treatment strategies on clinical outcomes in men with cT3 prostate carcinoma.

KEYWORDS

prostate cancer, locally advanced disease, treatment patterns, health disparities, marriage

INTRODUCTION

Initial interventions to achieve local control and possible cure for the treatment of clinically advanced (cT3) prostate cancer include external beam radiotherapy (EBRT) and radical prostatectomy (RP), either singly or combined. In general these treatments are given with neoadjuvant and/or adjuvant hormonal therapy. Recent randomized trials have shown that EBRT with adjuvant androgen-deprivation therapy significantly improved local and distant control and survival compared with EBRT alone [1–3]. This combination, endorsed by the USA National Cancer Institute (NCI), is now the most commonly recommended treatment for men with cT3 prostate carcinoma [4]. RP is not currently recommended as first-line therapy, although ongoing adjuvant chemo-hormonal trials might change this recommendation [5,6]. Thus far, observational studies suggest that RP can be beneficial for lower-risk (cT3a) disease (i.e. in men with a PSA level of <10 ng/

mL, low to moderate Gleason grade, and no evidence of lymph node or seminal vesicle involvement) [4,7,8].

Little is known about clinical and sociodemographic predictors of RP and RT for the local treatment of clinically advanced prostate carcinoma. We used population-based data from the Surveillance, Epidemiology and End Results (SEER) cancer registries to characterize recent practice patterns, and to identify the clinical and sociodemographic predictors of local treatment for cT3 disease.

PATIENTS AND METHODS

We used the population-based public-use data available through the SEER cancer registries to identify men with cT3 prostate cancer. Sponsored by the NCI, the SEER registries document all incident cases of cancer for ≈ 14% of the USA population. SEER registries comprise nine geographical regions:

five states (Connecticut, Hawaii, Iowa, New Mexico and Utah) and four urban areas (San Francisco-Oakland, Seattle, Atlanta and Detroit). We analysed data collected on sociodemographic characteristics, including patient age at date of diagnosis, race/ethnicity (non-Hispanic white, black, Hispanic (a US citizen or resident of Latin American or Spanish descent), and other), marital status (currently married, not married, unknown), and SEER registry where the diagnosis was made; tumour grade and stage; and therapy received within 4 months of diagnosis.

We included men with a primary diagnosis of locally advanced, lymph-node negative disease made between the years 1995 and 2001 (the most recent years available). Beginning in 1995, SEER added a field to distinguish clinical from pathological staging, replacing what had previously been a single summary field that contained information about either clinical or pathological staging if the latter had been obtained. Men were

excluded if the diagnosis was made at autopsy or on the death certificate, or if data pertaining to patient age or tumour stage or grade were unavailable. Based on these criteria, there was a total of 3382 patients.

Tumour stage was based on the SEER/American Joint Commission on Cancer extent of disease ('EOD 10 Prostate pathology ext 1995+') variable corresponding to clinically locally advanced (cT3) disease. Tumour grade was categorized as low, moderate or high, corresponding to Gleason scores of 2–4, 5–7 and 8–10. PSA levels were not included because these are unavailable in SEER. The choice of primary local therapy was based on SEER data and was defined as prostatectomy if indicated by the site-directed surgery variable (TURP procedures were excluded), as RT if indicated by any form of EBRT or brachytherapy, and as no aggressive local therapy (generally expectant management or hormonal manipulation only) if neither surgery nor RT were reported. We defined aggressive treatment as either surgery or RT.

We evaluated the factors associated with receiving aggressive local treatment using the following predictor variables: patient age, tumour stage, tumour grade, race/ethnicity, marital status, year of diagnosis, and SEER registry. Descriptive analyses, univariate and multiple logistic regression models were used; the outcome variables were dichotomous, i.e. (i) RP vs RT and (ii) aggressive therapy (RP or RT) vs expectant management/hormonal manipulation alone. We determined *a priori* that the independent variables in the logistic models would be those significantly associated with initial therapy in the bivariate analysis, by using a statistical significance level of 0.25. We also examined statistical interactions of age and grade, race and grade, age and marriage, age and race, and race and marriage; none of these interaction terms was significant. Results of the logistic regression models are shown as absolute percentages of patients receiving the treatment of interest and risk ratios associated with each independent variable adjusted for the others. Risk ratios were computed as corrections of the adjusted odds ratios [9].

RESULTS

The sociodemographic and clinical characteristics of the study cohort are shown

Cohort	All men	Treatment		
		RP	EBRT	WW/HT
Number of patients	3382	415	1799	1168
Age category in years, %				
<55	8.3	29.6	51.3	19.0
55–59	9.1	22.7	55.9	21.5
60–64	15.5	20.9	55.5	21.5
65–69	22.3	13.9	61.5	24.6
70–74	23.3	8.9	56.6	29.6
75–79	16.4	3.8	54.0	42.2
≥80	5.1	2.0	23.2	74.8
Gleason grade, %				
2–4	1.8	14.5	58.2	27.3
5–7	55.1	13.7	58.5	27.8
8–10	43.0	11.3	50.1	38.6
Clinical stage, %				
T3a	50.7	12.3	56.5	31.2
T3b (seminal vesicle)	34.0	13.6	52.9	33.5
T3 (periprostic, NOST)	15.3	9.7	45.1	45.2
Race/ethnicity, %				
White	78.8	13.0	54.8	32.1
Black	10.3	11.6	47.9	40.5
Hispanic	4.0	7.2	56.5	36.2
Other	6.9	9.7	46.5	43.9
Marital status, %				
Married	77.4	13.6	56.6	29.8
Not	22.6	10.7	48.2	41.1
SEER registry, %				
San Francisco/Oakland	24.4	11.0	54.4	34.6
Connecticut	8.5	12.7	48.9	38.4
Detroit	14.4	13.5	57.0	29.6
Hawaii	4.5	6.5	47.3	46.2
Iowa	12.3	11.7	53.2	35.1
New Mexico	4.1	12.2	53.2	34.5
Seattle	17.9	14.2	48.4	37.3
Utah	6.3	6.1	58.9	35.1
Atlanta	7.6	20.8	60.4	18.8

TABLE 1

Sociodemographic and clinical characteristics of 3382 men with clinically staged, locally advanced prostate carcinoma

Treatment refers to the % of men who received as primary local therapy RP, any form of EBRT or brachytherapy, or systemic therapy only, consisting of conservative management (WW) or hormonal manipulation (HT). Married refers to the % of men currently married; Gleason Grade corresponds to Gleason score (well-differentiated = 2–4; moderately differentiated = 5–7; poor or undifferentiated = 8–10). †Not otherwise specified.

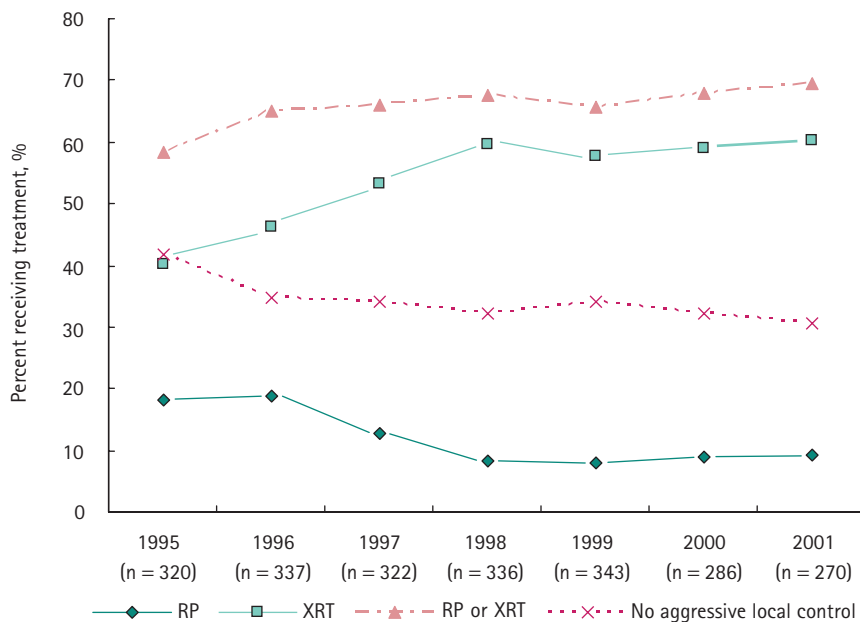
in Table 1. Within the cohort, 12.3% underwent RP, 53.2% received RT (overwhelmingly EBRT), and the remainder (34.5%) had hormonal manipulation or expectant management but no local therapy. Younger men were more likely to have RP, with almost 30% of men aged <55 years having RP compared with only 2% of men aged ≥80 years.

In 2001, the most recent year for which data were available, and among men aged <70 years (the group most likely to receive some form of aggressive therapy), 16.3% had RP and 23.2% had no therapy for local control. Compared with non-Hispanic white men, black men had similar rates of RP (13.0% vs 11.6%) but were less likely to have local

treatment in general (RT or RP; 59.5% vs 67.8%, $P = 0.01$). Married and unmarried men had similar rates of RP, but married men were more likely to receive any form of local therapy (70.2% vs 58.9%, $P < 0.001$). Finally, rates of RP among patients with seminal vesicle involvement and high-grade tumours were 13.6% and 11.3%, respectively.

Figure 1 shows the temporal trends in therapy for cT3 prostate carcinoma over a 6-year period between 1995 and 2001. Rates of aggressive local treatment (RP or RT) increased by 11% (58.4% to 69.4%). This corresponded with a halving in the frequency of RP (18.1% to 9.3%) and a 20% absolute increase in RT (40.3% to 60.2%). The period between 1995 and 1998 represented that

FIG. 1. Therapeutic trends for local control of cT3 prostate carcinoma.



with the most rapid change, after which treatment patterns stabilized.

The results of the multivariate analyses, shown in Tables 2 and 3, give the adjusted risk ratios for receiving RP vs RT vs any local therapy (RP or RT) vs only hormonal manipulation or expectant management. Younger age was the strongest predictor of RP over RT, and any form of aggressive treatment vs none. Black and unmarried men had a significantly lower relative risk of receiving any local therapy than non-Hispanic whites and married men, respectively. Men with high-grade tumours were significantly less likely than men with lower-grade tumours to receive local therapy. Finally, there was some regional variability, with having any local therapy less frequent in San Francisco/Oakland, Connecticut and Iowa than in the other SEER registries.

DISCUSSION

Population-based SEER data showed that the proportion of men receiving local therapy for locally advanced prostate cancer increased by 11% (58% to 69%) from 1995 to 2001. During this period, particularly between 1995 and 1998, fewer men had RP while a substantially higher proportion had RT. Younger age was a strong predictor of having both any local therapy and RP, specifically. Older men, black men, unmarried men and men with higher-grade tumours were significantly less likely than their counterparts to have any local therapy. These treatment patterns are very similar to those of clinically localized (cT1/T2) disease, in which significant predictors have included tumour stage and grade, SEER registry, and patient age, race/ethnicity and marital status [10,11].

Almost a quarter of men aged <70 years in the 2001 had no local therapy for their cT3 prostate cancer. This is potentially of concern, although we do not know what proportion of these men had significant comorbidities, were unwilling to accept local therapy when offered, received delayed local treatment, or did not receive recommendations for local therapy from their urologists or radiation oncologists.

Because RP is the most aggressive form of therapy it is often considered the most definitive. This impression might explain why

Variable/model	Overall relative risk (95% CI)	<i>TABLE 2</i> <i>A summary of logistic regression predicting RP vs RT for local control of cT3 prostate carcinoma</i> <
----------------	--------------------------------	--

it is sometimes favoured in younger men whose anticipated life-span is greatest. 'Getting the tumour out' and using surgical pathology to 'know what one is dealing with' might be preferred over allowing the tumour to remain within the body without knowing the pathological stage, as happens with RT. When RP is used for local control, surgical staging has been shown to be clinically valuable. Recent results from the randomized multicentre Southwest Oncology Group (SWOG) study 8794 indicate that immediate adjuvant RT after RP in the setting of surgically staged T3 carcinoma is better than a 'wait-and-see' approach after RP [12]. However, it is unclear for both younger and older patients whether the clinical outcomes associated with this approach are better than those that could be obtained with RT and androgen deprivation only.

The proportion of men with cT3 disease who had RP halved from 1995 to 2001. The future use of RP is uncertain. One small phase II study (SWOG 9109) showed favourable outcomes associated with neoadjuvant antiandrogen therapy before RP for clinical T3/T4 prostate carcinoma [13]. However, at least three randomized trials evaluating 3 months of neoadjuvant androgen deprivation before RP in patients with T1–T3 disease failed to show better outcomes for cancer control [14–16]. Two ongoing adjuvant chemo-hormonal trials after RP (SWOG 9921 and Veterans' Affairs Cooperative Study #553) [5,6] might show that patients with high-risk characteristics have very favourable outcomes.

A recent case series reported comparable 15-year cancer control and survival outcomes with RP for cT3 and cT2 disease [17]. However, in that retrospective study the mean preoperative PSA level of patients with cT3 disease was only 10.2 ng/mL, and the proportion of patients with clinical seminal vesicle involvement was not reported. In addition, the study was limited to cases within a single tertiary referral centre, and there was significant heterogeneity in the receipt and timing of neoadjuvant hormonal therapy, as well as adjuvant and salvage hormonal therapy and RT.

Only one very small randomized trial compared RP against EBRT using hormonal ablation both before and after primary therapy in stage T2c and T3 prostate carcinoma [18]. That study showed no

Variable/model	Overall relative risk (95% CI)	TABLE 3 A summary of logistic regression predicting any aggressive (RP or RT) vs no local control therapy for cT3 prostate carcinoma
Total number	3382	
Age category, years		
<55	1.42 (1.02–1.91)*	*Variables that retained significance in stepwise logistic regression; original predictor variables included patient age, tumour stage, tumour grade, race/ethnicity, marital status, year of diagnosis, and SEER registry. †Not otherwise specified.
55–59	1.25 (0.92–2.09)	
60–64	1.24 (0.97–1.56)	
65–69 (reference)		
70–74	0.80 (0.65–0.97)*	
75–79	0.59 (0.48–0.71)*	
≥80	0.33 (0.26–0.41)*	
Race/ethnicity		
White (reference)		
Black	0.56 (0.45–0.69)*	
Hispanic	0.75 (0.54–1.01)	
Other	0.81 (0.62–1.01)	
Married		
	1.33 (1.18–1.87)*	
Gleason grade		
2–4	0.97 (0.56–1.53)	
5–7 (reference)		
8–10	0.73 (0.66–0.90)*	
Clinical stage		
T3a (reference)		
T3b (seminal vesicles)	0.89 (0.78–1.02)	
T3 (periprostatic, N0S†)	0.74 (0.63–0.86)*	
SEER registry		
San Francisco/Oakland	0.79 (0.62–0.98)*	
Connecticut	0.44 (0.30–0.63)*	
Metro Detroit (reference)		
Hawaii	0.78 (0.54–1.03)	
Iowa	0.69 (0.53–0.89)*	
New Mexico	0.74 (0.49–1.04)	
Seattle	0.82 (0.65–1.02)	
Utah	0.77 (0.55–1.04)	
Metro Atlanta	1.23 (0.83–1.76)	

difference in 5-year survival, but higher levels of late morbidity and a lower quality of life in the RP arm. However, the long-term adverse effects of RT remain to be assessed. A recent retrospective analysis of a large group of patients found a 1.7-fold increase in rectal cancer compared to patients having surgery only [19], although another epidemiological study found no such effect [20]. Considerations such as these might lead some urologists to counsel their patients on what they perceive are advantages of surgery, especially in younger men.

The finding that black and unmarried men were less likely to receive local therapy might be attributable to higher levels of comorbidity in these groups. Unfortunately, comorbidities were not recorded in this dataset. However, in a separate study of treatment patterns for T1/T2 disease, married men with no known

comorbidities were significantly more likely to receive aggressive therapies than a similar cohort of unmarried men [10]. Possibly, married men or their wives advocate therapy that they perceive as most likely to give a cure, whereas unmarried men are less likely to have social supports encouraging aggressive interventions. Clinicians might also recommend aggressive therapies more strongly or more often to married than unmarried men. The perceived ability of wives to help care for patients during and after treatment might play a role. The influence of spouses on treatment decision-making deserves greater scrutiny, as it appears to be pervasive in treatment choices for other stages of prostate cancer [10].

On balance, studies evaluating RT have included more patients than those evaluating

RP. To determine the optimum treatment of cT3 disease, larger trials of RP are needed and, ideally, there should be trials that directly compare surgery and RT as parts of multimodal treatment regimens that incorporate hormonal therapy and/or chemotherapy. Clinical downstaging is possible with RP, but because upstaging is more likely these trials should also consider how often RP results in the need for salvage RT.

The present study of treatment patterns has several limitations. First, regardless of whether a patient received therapy for local control, we assumed that all patients received hormonal manipulation, because this is a standard of care. However, information on hormonal therapy was unavailable in the dataset, so possibly a proportion of cases had no systemic treatment. In addition, SEER only captures primary therapy received within 4 months of diagnosis. Therapy provided after this period would have resulted in an ascertainment bias that could, e.g. have differentially affected black men, unmarried men, older men, or any other particular group. Information about PSA levels, comorbidities, and socio-economic status was also lacking; including this information would have made the analyses more robust. Finally, because comorbidities were not recorded in the dataset, results are suggestive of, but inconclusive, for the presence of disparities by race/ethnicity and marital status in receipt of any aggressive local treatment. Despite these limitations we showed that rates of local-control interventions for cT3 prostate carcinoma increased over a recent 6-year period, and that these changes corresponded with declining rates of RP and increasing rates of RT.

ACKNOWLEDGEMENTS

This study was supported in part by a *Redes en Acción* research subcontract from the Baylor College of Medicine, funded by a Special Populations Network NCI grant (U01CA86117), Amelie G. Ramirez, DrPH (PI). This study used the SEER database. The interpretation and reporting of these data are the sole responsibility of the authors. The authors acknowledge the efforts of the Applied Research Program, NCI and the SEER Program tumour registries in the creation of this database.

CONFLICT OF INTEREST

None declared. Source of funding: NCI U01CA86117.

REFERENCES

- 1 Pilepich MV, Krall JM, al-Sarraf M *et al.* Androgen deprivation with radiation therapy compared with radiation therapy alone for locally advanced prostatic carcinoma: a randomized comparative trial of the Radiation Therapy Oncology Group. *Urology* 1995; **45**: 616–23
- 2 Syed S, Petrylak DP, Thompson IM. Management of high-risk localized prostate cancer: the integration of local and systemic therapy approaches. *Urol Oncol* 2003; **21**: 235–43
- 3 Seidenfeld J, Samson DJ, Aronson N *et al.* Relative effectiveness and cost-effectiveness of methods of androgen suppression in the treatment of advanced prostate cancer. *Evid Rep Technol Assess (Summ)* 1999; **4**: 1–246
- 4 National Cancer Institute. Stage III Prostate Cancer. Prostate Cancer PDQ®: Treatment, December 8, 2005. Available at: <http://www.nci.nih.gov/cancertopics/pdq/treatment/prostate/HealthProfessional/page7>. Accessed March 2006
- 5 Southwest Oncology Group. S9921 – Phase III intergroup. Adjuvant androgen deprivation versus mitoxantrone plus prednisone plus androgen deprivation in selected high risk prostate cancer patients following radical prostatectomy, phase III, 1999. Available at: <http://www.swog.org/Visitors/ViewProtocolDetails.asp?ProtocolID=64>. Accessed March 2006
- 6 Department of Veterans Affairs. CSP #553 Chemotherapy after prostatectomy (CAP) for high risk prostate carcinoma. A phase III randomized study. Clinical Trials.gov identifier: NCT00132301. Available at: <http://www.clinicaltrials.gov/ct/show/NCT00132301>. Accessed March 2006
- 7 Gerber GS, Thisted RA, Chodak GW *et al.* Results of radical prostatectomy in men with locally advanced prostate cancer: multi-institutional pooled analysis. *Eur Urol* 1997; **32**: 385–90
- 8 Van Poppel H, Goethuys H, Callewaert P, Vanuytsel L, Van de Voorde W, Baert L. Radical prostatectomy can provide a cure for well-selected clinical stage T3 prostate cancer. *Eur Urol* 2000; **38**: 372–9
- 9 Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA* 1998; **280**: 1690–1
- 10 Denberg TD, Beaty BL, Kim FJ, Steiner JF. Marriage and ethnicity predict treatment in localized prostate carcinoma. *Cancer* 2005; **103**: 1819–25
- 11 Hoffman RM, Harlan LC, Klabunde CN *et al.* Racial differences in initial treatment for clinically localized prostate cancer. Results from the prostate cancer outcomes study. *J Gen Intern Med* 2003; **18**: 845–53
- 12 Jancin B. Radiation improves advanced prostate cancer's outcomes. In *Internal Medicine News*, Vol. 38 (22). Morristown, NJ: Elsevier, 2005: 1, 6
- 13 Powell IJ, Tangen CM, Miller GJ *et al.* Neoadjuvant therapy before radical prostatectomy for clinical T3/T4 carcinoma of the prostate: 5-year followup, Phase II Southwest Oncology Group Study 9109. *J Urol* 2002; **168**: 2016–9
- 14 Soloway MS, Pareek K, Sharifi R *et al.* Neoadjuvant androgen ablation before radical prostatectomy in cT2bNxMo prostate cancer: 5-year results. *J Urol* 2002; **167**: 112–6
- 15 Aus G, Abrahamsson PA, Ahlgren G *et al.* Three-month neoadjuvant hormonal therapy before radical prostatectomy: a 7-year follow-up of a randomized controlled trial. *BJU Int* 2002; **90**: 561–6
- 16 Bono AV, Pagano F, Montironi R *et al.* Effect of complete androgen blockade on pathologic stage and resection margin status of prostate cancer: progress pathology report of the Italian PROSIT study. *Urology* 2001; **57**: 117–21
- 17 Ward JF, Slezak JM, Blute ML, Bergstralh EJ, Zincke H. Radical prostatectomy for clinically advanced (cT3) prostate cancer since the advent of prostate-specific antigen testing: 15-year outcome. *BJU Int* 2005; **95**: 751–6
- 18 Akakura K, Isaka S, Akimoto S *et al.* Long-term results of a randomized trial for the treatment of Stages B2 and C prostate cancer: radical prostatectomy

versus external beam radiation therapy with a common endocrine therapy in both modalities. *Urology* 1999; **54**: 313–8

- 19 **Baxter NN, Tepper JE, Durham SB, Rothenberger DA, Virnig BA.** Increased risk of rectal cancer after prostate radiation: a population-based study. *Gastroenterology* 2005; **128**: 819–24

- 20 **Movsas B, Hanlon AL, Pinover W, Hanks GE.** Is there an increased risk of second primaries following prostate irradiation? *Int J Radiat Oncol Biol Phys* 1998; **41**: 251–5

Correspondence: Thomas Denberg, 4200 E. 9th Ave., B-180, Division of General Internal Medicine, University of Colorado

Health Sciences Center, Denver, CO 80262, USA.
e-mail: tom.denberg@uchsc.edu

Abbreviations: **(EB)RT**, (external beam) radiotherapy; **RP**, radical prostatectomy; **NCI**, National Cancer Institute; **SEER**, Surveillance, Epidemiology and End Results; **SWOG**, Southwest Oncology Group.

1. How does patient preference for cure and treatment side effects influence urologist recommendations for watchful waiting versus aggressive therapy in an elderly patient (age 77) with moderate grade (Gleason 3+3) localized prostate carcinoma?

2.

Key:

Version 1 - SE-/Cure+

Version 2 - SE+/Cure+

Version 3 - SE-/Cure-

Version 4 - SE+/Cure-

Cure - : "Cure is not as important as enjoying life – everyone has to die sometime."

Cure + : "Cure is the most important thing – I want to see my five-year-old grandson graduate from high school."

SE - : "I would not be greatly bothered by urinary leakage and could wear pads if I had to. As far as sex is concerned, my wife and enjoy it but could easily adjust to living without it."

SE + : "I would be greatly bothered by urinary leakage of any sort. As far as sex is concerned, my wife and I continue to enjoy it and I do not want any impairment in my erectile function."

Tx	1 SE-/Cure+	2 SE+/Cure+	3 SE-/Cure-	4 SE+/Cure-	Total
WW	42 15.56	98 32.03	108 38.43	209 65.52	457 38.86
RP/XRT	228 84.44	110 67.97	173 61.57	208 34.48	719 61.14
Total	270 100.00	306 100.00	281 100.00	319 100.00	1176 100.00

Pearson chi2(3) = 163.1634 Pr = 0.000

Logit: predict WW using SE and Cure and SW*Cure

Tx (WW)	Odds Ratio	Std. Err.	z	P> z	[95% Conf. Interval]
SE+ (v SE-)	3.043519	.5175342	6.545	0.000	2.180889 4.247352
Cure - (v Cure+)	4.032653	.6854012	8.204	0.000	2.890136 5.626826
SE*Cure	.8403735	.2256876	-0.648	0.517	.4964515 1.422551

Interpretation:

1. Minimal patient concern about side effects seems to have a similar influence on urologist treatment recommendation for RP/XRT as patient desire for "cure"; together, the two are additive.
2. High proportion of urologist treatment recommendation for RP/XRT when patient desires cure (>68%) seems to overemphasize the actual benefit of "cure." In an elderly patient, there is little survival benefit of aggressive therapy but a high likelihood of side effects.
3. Urologists should be more cautious about making treatment recommendations for RP/XRT on the basis of elderly patient preference for "cure." Recognize that it is difficult to avoid action orientation ("do something"), especially when patient seems to imply this desire through use of the word "cure."

SECTION 1:

Vignette 1: Please consider the following information and then offer a treatment recommendation:

Patient: 77 year-old white male

Social: Married, retired furniture salesman, lives close to a major medical center, no transportation barriers.

Insurance: Medicare

Diagnosis: Localized (organ-confined) prostate cancer (TRUS=DRE)

Gleason grade: 3+3

Biopsy: 2 out of 12 cores on the left each had 10% tumor

PSA: 5.4 (obtained by primary care provider)

CT scan: No evidence of regional lymph node involvement

Bone scan: Negative

Prostate size: 30 grams

Family history of prostate cancer: None



AUA symptom score: 7 (i.e. mild urinary symptoms)

Sexual function: Normal erections satisfactory for intercourse

Comorbidities: Gout, on allopurinol and a daily aspirin. Otherwise healthy and active.

Patient concerns: Patient understands the potential side effects of all treatment alternatives.

He says, “cure is not as important as enjoying life – everyone has to die sometime.”

He also says, “I would not be greatly bothered by urinary leakage and could wear pads if I had to. As far as sex is concerned, my wife and I enjoy it but could easily adjust to living without it.”

He is anxious to know your treatment advice and is willing to carry through with anything you recommend.

Given the following four options only, please indicate which one you are *more likely* to recommend (**mark only one answer**):

____ Radical prostatectomy with optional nerve sparing

____ A form of radiation: ____brachytherapy OR ____external beam

____ Observation (or “watchful waiting”)

____ Cryotherapy

TITLE: Side effects of radical prostatectomy: Urologist perceptions in a nationally-representative survey

Goals:

- (1) Characterize urologist beliefs about RP side effects in order to gain insight into how they might represent the procedure to patients.
- (2) Identify predictors of these beliefs based on urologist sociodemographic and clinical practice characteristics.
- (3) Compare urologist beliefs to published outcome data, including 2-year (conservative) and 5-year PCOS data and data from other studies.

Note that PCOS provides the most comprehensive, longitudinal, patient-reported perspective of outcomes of care received in community practice. Other, relatively recent studies have also employed larger sample sizes and patient-reported measures.

These more recent outcome studies are different from earlier ones. Earlier outcome data, especially Johns Hopkins data from Walsh, may be misleading because outcomes were generally assessed and interpreted by surgeons rather than patients, sample sizes were relatively small, patients were highly selected, community practices were under-represented, and assessment criteria were limited. Single center reports, especially from earlier series,¹⁻³ for example, quote impotence rates of 28-37%, markedly less than what has been reported in more recent, community-based or multi-institutional series and after the advent of medications such as sildenafil.

Problems with PCOS, especially at 5 years, include selection bias from loss to follow-up. There is also potential recall bias related to pre-treatment symptoms (although a sub-study has shown that recall is fairly accurate). Finally, PCOS was unable to determine the surgical volume or expertise of individual urologists. In reporting outcomes from the published literature, we will refer to a variety of studies but will give precedence to PCOS because it is the highest quality outcome study to date. We will include 2 year PCOS data for more conservative estimates of outcomes because non-responders at 2 years were considered to have good outcomes.

We assess urologist beliefs in three areas using seven survey items.

- A. “National” RP impotence and incontinence rates.
 - 1. With nerve-sparing prostatectomy, national rates of *any* form of long-term incontinence are...
 - 2. With nerve-sparing prostatectomy and oral phosphodiesterase-5 enzyme inhibitor treatment (e.g. Viagra), average national rates of long-term impotence (inability to sustain an erection for intercourse) are...

<=25%	26-50%	51-74%	>=75%
-------	--------	--------	-------
- B. Urologist’s own perceived impotence and incontinence rates relative to a perceived “national” average.
 - 3. Different urologists treat different patient populations. Compared with the national average, your *own* surgical rate of long-term incontinence associated with nerve-sparing prostatectomy is...
 - 4. Compared with the national average, your *own* surgical rate of long-term impotence associated with nerve-sparing prostatectomy is...

lower	about the same	higher
-------	----------------	--------
- C. Comparisons between RP and ECR in terms of cure, impotence, and incontinence outcomes.
 - 5. For Gleason grade 8-10 localized prostate cancers, rates of cure are higher / the same / lower with prostatectomy compared with radiation (external beam or seeds)
 - 6. In general, prostatectomy has equal or better long-term urinary incontinence outcomes than external conformal beam radiation...
 - 7. In general, prostatectomy has equal or better long term impotence outcomes than external conformal beam radiation...

true	false
------	-------

These domains are relevant because most urologists assign the greatest importance to addressing patient questions about major treatment morbidity and cure rates.⁴

Potential predictors of beliefs:

- a. # prostatectomies/year (surgical volume)
- b. completion of urologic oncology fellowship
- c. academic vs. private practice
- d. years practicing urology
- e. population of town/city in which practice is located
- f. urologist-affiliated hospital bed size
- g. >40% black/Latino patients in practice

Rationale for including:

a-d: surgical volume, clinical training, clinical setting, and years in practice influence beliefs about RP and about one's own skills.

e-f: population of town/city and hospital bed size are proxies for frequency of contact with other urologists and multidisciplinary specialists in PCa.

g: significant black/Latino patient population could influence urologist beliefs about impotence outcomes, in particular, because of cultural factors and preferences in these patient groups

These predictors were assessed in bivariate analyses and then multivariate logistic regression. All logistic regressions were run with variables that were significant in the bivariate analyses at $p=0.25$ or less, then backward stepwise regression was done.

Methods:

Physicians who listed their specialty as urology were selected from the American Medical Association Masterfile. Because not all urologists treat prostate cancer, we limited our sampling to urologists who were also listed in the National Drug Council (NDC) database as prescribers of hormonal therapies (the All Antineoplastic Antimetabolites therapeutic class). Based on AMA data fields, we also excluded trainees, pediatric urologists, and urologists not involved in patient care. A total of 6,104 urologists met the above criteria. Of these, a random sample of 2,000 urologists was selected to receive a mailed survey. These criteria were designed to produce a nationally representative sample of urologists directly involved in the treatment of prostate carcinoma.

An initial letter was mailed specifying that the survey would arrive in approximately one week. A week later, urologists received the survey, an explanatory letter, a \$10 incentive, and a postage-paid return envelope. A reminder letter was sent a week later. Urologists who failed to return the survey after a month received another copy of the survey with a reminder letter. Non-respondents at two months received by overnight post a third and final copy of the survey. Urologists were asked to indicate on a postage-paid return postcard whether they were retired or did not wish to participate in the study. In the former case, they were removed from the denominator; in the latter case, no further mailings were sent. In the event that a non-completed survey was returned by the post office with a bad address and a correct address could not be determined, the urologist was replaced by another urologist who practiced in the same town or city.

The survey collected information about sociodemographic and clinical practice characteristics of the responding urologist. In seven items, it also asked urologists to specify beliefs about potency and continence outcomes associated with radical prostatectomy and in relation to radiotherapy.

Table 1

Respondents	1,306 (out of 1,985 non-retired)
Response rate	65.8%
Male %	97.9
Mean age, yr (SD)	51.9 (10.3)
Mean yrs in practice (SD)	19.5 (10.2)
Race/ethnicity %	
Caucasian	83.3
African-American	1.9
Latino	2.1
Asian/ Pacific Islander	10.5
Other	2.1
Completed fellowship %	7.1
Type of Practice (%)	
Academic	7.0
Private	93.0
Average number prostatectomies % year	
None	10.9
1-10	33.1
11-30	41.8
>30	14.2
Average number brachytherapies % year	
None	32.1
1-10	26.4
11-30	32.3
>30	9.1
Hospital bed size of practice (%)	
<100 beds	7.8
101-300 beds	64.9
>300	27.2
City size of practice %	
1-9,999	10.6
10,000-99,999	53.4
100,000-499,999	23.2
500,000-999,999	4.6
>1,000,000	8.1
Race of Patient Population %	
<10% African-American	52.3
10-30% African-American	36.6
31-60% African-American	9.9
>60% African-American	1.2
Race of Patient Population %	
<10% Latino	72.1
10-30% Latino	22.7
31-60% Latino	4.3
>60% Latino	0.0

NO DIFFERENCES between respondents (n=1306) and non-respondents (n=679) in terms of all tested variables: gender, hormone-rx'ing decile, practice type, population of city of clinical practice, region of country, year of birth, years in practice. Only 20/1,306 respondents were in the lowest quintile of hormone prescribing and also indicated that they perform no prostatectomies or brachytherapies, meaning that 98.5% of the sample was meaningfully involved in the treatment of prostate carcinoma.

1. POPULATION-BASED IMPOTENCE RATES WITH RP

National rates of impotence (inability to sustain erection for intercourse) < 50% with nerve-sparing RP & Viagra:
endorsed by 68% of all urologists; no association w/ volume; no significant predictors in multivariable analysis.
(60% of urologists said impotence rates are between 25% and 50%.)

best available evidence:

PCOS⁵ (2005): (5 year) impotence = 71%; and of 81% potent at baseline, only 28% are potent 5 years out

PCOS⁶ (2000): (2-year) impotence = 60%; and of 73% potent at baseline, only 19% are potent at 2 years.

Either interpretation (absolute rates of long-term impotence versus impotence related directly to RP) would require a response that national long-term rates of impotence are > 50%. This is important because 46% of men call impotence a moderate to big problem at 5 years⁵ and 42% call it a moderate to big problem at 2 years.⁶

Three large community/multi-institutional outcome series within the last dozen years that used patient-centered measures report impotence rates between 73% and 89%, but there was heterogeneity with regard to when outcomes were assessed, use of erectile aids, and nerve-sparing.⁷⁻⁹

With regard to impotence after bilateral nerve-sparing, specifically, few studies and most – especially earlier series - have significant flaws:

Quinlan¹ (1991): Of 503 men with bilateral nerve-sparing, 24% are impotent (but single center, urologist rather than patient-centered assessment, and did not specify quality of erections – i.e. sufficient for intercourse)

Leandri¹⁰ (1992): Of 106 men with bilateral nerve-sparing, 29% are impotent (same shortcomings as above reference)

Catalona³ (1993): Of 236 men with bilateral nerve-sparing, 37% are impotent (same shortcomings as above)

Geary¹¹ (1995): Of 69 men with bilateral nerve-sparing, 69% are impotent (single center, but quality of erections was defined)

With regard to impotence with bilateral nerve sparing and with sildenafil, specifically, there have been few studies.

PCOS⁵ (2005): Of 192 men with bilateral nerve sparing and sildenafil, 51% are still impotent.

Schover¹² (2002): Of 240 men with bilateral nerve sparing and medical treatment (including but not limited to sildenafil) when needed, impotence was 67% at an average of 4.3 years post-tx.

Zippe¹³ (2000): Of 53 men with bilateral nerve sparing and sildenafil, impotence was only 28%. However, the mean age of these patients was only 61 years, they were from a single center of excellence, and the sample size was small.

Conclusion: On balance, a majority of urologists, the vast majority of whom are community-based, have overly optimistic attitudes about potency outcomes with RP, even with sildenafil. There is no association with surgical volume, academic practice, years in practice, or urologic oncology fellowship. These findings raise concerns that a significant proportion of urologists *may* not represent to patients an accurate or complete account of the potency outcomes associated with RP.

2. UROLOGIST PERCEIVED IMPOTENCE OUTCOMES IN ABSOLUTE AND RELATIVE TO AVERAGE

One's own rates of long-term impotence in absolute terms and in comparison with national average:

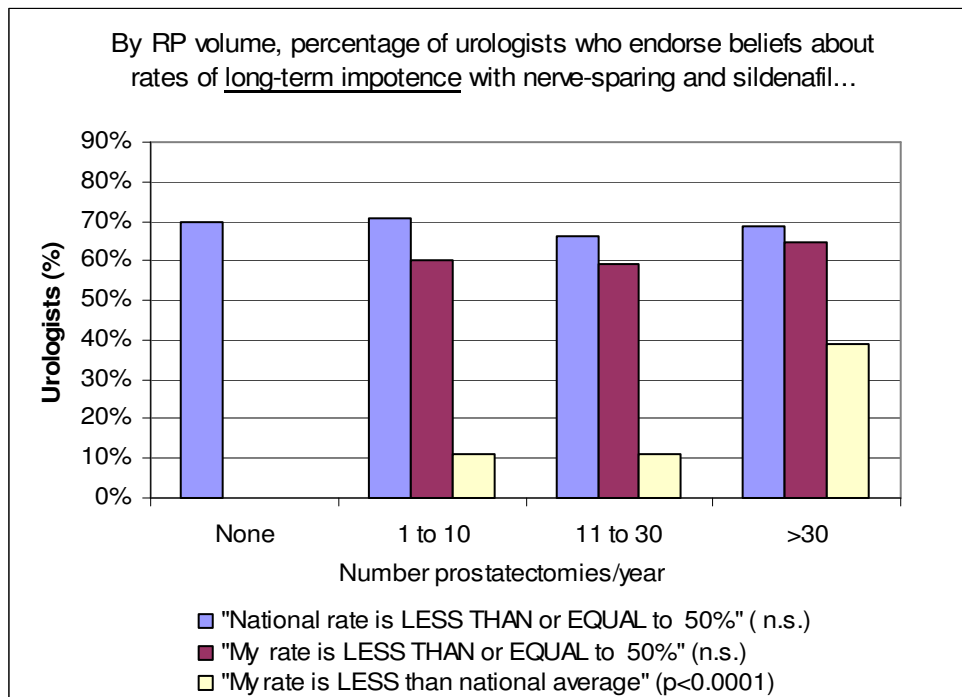
60% of urologists overall, without difference by surgical volume, reported that their own rates of long-term impotence were $\leq 50\%$.

In terms of comparisons with the perceived national average, about 11% of urologists who do < 30 RP's compared with 39% of those who do >30 RP's said that their own rates of impotence were lower. Higher volume surgeons are more likely to believe their outcomes are better than average; the lower volume surgeons are less likely to believe this.

Self-comparison with national average: Impotence outcome	OR (95% CI)
Number of Prostatectomies per year	
11-30 vs. 1-10	1.03 (0.69-1.55)
>30 vs. 1-10	5.25 (3.42-8.06)*

Conclusion: A majority of urologists in all surgical volume categories (60% overall) said their own rates of impotence were less than 50%, which does not correspond with the evidence and suggests that a majority of urologists may dramatically overrate their potency outcomes.

Among lower-volume urologists, only 11% claim their impotency outcomes are better than average compared with 39% of high-volume urologists. This volume – belief relationship is significant. **This particular “Lake-Wobegon” effect is relatively small compared with some of the other items and deserves interpretation/speculation.**



3. POPULATION-BASED INCONTINENCE RATES WITH RP

National rates of any form of long-term incontinence are <25% with nerve-sparing RP:

{Note: no evidence that nerve-sparing improves continence rates.}

endorsed by 70% of all urologists (*no association by volume*)

important issue: how do respondents interpret “any” long-term incontinence?

(1) “any” was emphasized in the question and was meant to imply any urinary leakage or use of pads. Best available evidence:

PCOS⁵: (5 year) incontinence (i.e. any dribbling) = 65% / (use of pad >=1/day) = 26%

PCOS⁶: (2 year) incontinence (i.e. any dribbling) = 49% / (use of pad >= 1/day) = 22%

Also:

Kao⁹ (1069 pts.), community study: (min. 6 months post-RP) incontinence (i.e. any use of pad/diaper) = 33%

Sebesta¹⁴ (674 pts), community study: (min. 18 months post-RP, all<65 years) incontinence (i.e.any use of pad/diaper)=32%

Fowler⁸ (739 pts in US sample, all>65), community study: incontinence (i.e. any use of pad/diaper) = 30%

Aristotelis¹⁵ (70 pts, 12 months post-RP), single center, incontinence (i.e. any use of pads) = 33%

Geary¹⁶ (481 pts, min 12 months post-RP), single center, two surgeons, incontinence (i.e. any use of pads) = 20%

But,”any” urinary leakage could have also been interpreted as:

(2) any “significantly bothersome” (to the patient) urinary dribbling

PCOS⁵: (5 year) incontinence (i.e. moderate to big problem) = 13%

PCOS⁶: (2 year) incontinence (i.e. moderate to big problem) = 9%

(3) anything more than occasional leakage (i.e. frequent or no control)

PCOS⁵: (5 year) incontinence (i.e. frequent leakage/no control) = 14%

PCOS⁶: (2 year) incontinence (i.e. frequent leakage/no control) = 9%

Hautmann¹⁷: (1 year) incontinence (i.e. more than occasional leakage) = 20%.

In sum: the response that long-term incontinence is < 25% would be justified only for interpretations (2) and (3). This ambiguity is a potential limitation of the survey item. Nonetheless, quoting rates < 25% might suggest that some urologists favor definitions (2) and (3). If so, this should be made clear to patients.

Initial variables: >60% NHW in practice, numprost, population, bedsize, years_prac, fellowship

	OR (95% CI)
Academic	0.59 (0.37-0.94)*
Number of years practicing urology	
10-19 yrs vs. 0-9 yrs	0.83 (0.59-1.17)
20-29 yrs vs. 0-9 yrs	1.03 (0.73-1.47)
30+ yrs vs. 0-9 yrs	1.63 (1.08-2.45)*

Conclusion: A large majority of urologists believe that rates of “any” urinary incontinence following surgery are <25% -- this response is valid for particular interpretations of “any incontinence” but is off the mark for the intended interpretation. These findings raise concerns that a significant proportion of urologists *may* represent to patients an inaccurate or incomplete account of the incontinence outcomes associated with RP.

Interestingly, there is no association between this belief and surgical volume or urologic oncology fellowship. Academic urologists are less likely to endorse this belief than private-practice urologists. Urologists who have been in practice for more than 30 years are significantly more likely than those in practice < 30 years to endorse this belief.

Interpretation...

4. UROLOGIST PERCEIVED INCONTINENCE OUTCOMES IN ABSOLUTE AND RELATIVE TO AVERAGE

One's own rates of long-term incontinence in absolute terms and in comparison with national average:

67% of all urologists, without relation to surgical volume, reported their own incontinence rates were $\leq 25\%$.

Beliefs that one's own incontinence rate were lower than the perceived national average were endorsed by 56% of all urologists; by 43% of urologists doing 1-10 RP's/year and 81% of urologists doing >30 RP's/year (\pm association w/ volume).

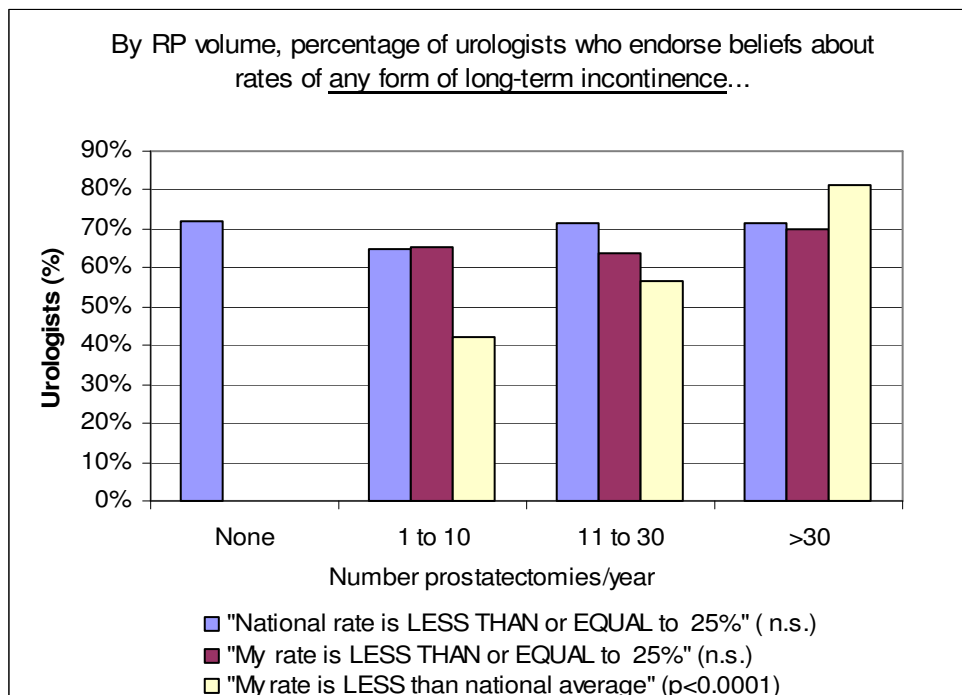
My own Incontinence Rates are Lower than National Average:

Initial variables: numprost, $>60\%$ NHW, region, fellowship

	OR (95% CI)
Number of Prostatectomies per year	
11-30 vs. 1-10	1.85 (1.42-2.42)*
>30 vs. 1-10	6.75 (4.36-10.46)*

Conclusion: A majority of urologists in all surgical volume categories (67% overall) said their own rates of incontinence were less than 25%, which does not correspond with the evidence applicable to interpretation (1) "any leakage or pads" although it is commensurate with interpretations (2) and (3).

Meanwhile, a large minority (43%) of low-volume urologists believe their incontinence outcomes are better than average compared with a large majority (81%) of high-volume urologists. These significant volume-related differences might be accurate if high-volume surgeons are more likely to treat younger patients. This is because potency and continence outcomes are superior in younger compared with older patients.¹⁸ While there is evidence from a large national cohort study that high-volume hospitals attract younger patients, this relationship is not confirmed for high-volume surgeons.¹⁹ The tendency for higher-volume surgeons to believe their continence and potency outcomes are better than average might be reasonable based on enhanced surgical skill and a vast literature related to other kinds of surgical volume-outcomes. Unfortunately, in relation to RP, specifically, there have been very few studies on this topic and none have shown that potency and continence outcomes are related to surgical volume. A very large RP volume-outcome study²⁰ found that major post-op and late urinary complications (e.g. strictures, fistulas, bladder neck obstructions) were both inversely related to surgeon and hospital procedure volume. This study did not demonstrate, however, that continence outcomes were better. Two separate studies^{21 22} also failed to detect relationships between surgeon volume, on the one hand, and sexual function and incontinence, on the other. The lower impotence and incontinence rates quoted from series derived from single centers of excellence seem to provide the best support for superior outcomes in these settings; however, no direct comparisons between institutions of varying surgical volume, employing identical definitions of outcomes and research methodologies, have demonstrated this relationship. Thus, beliefs among higher-volume surgeons about their ability to achieve superior (relative to their peers) outcomes is expected and may even be true but this has not, thus far, been demonstrated.



5. RP VS. ECBR IN TERMS OF CURE

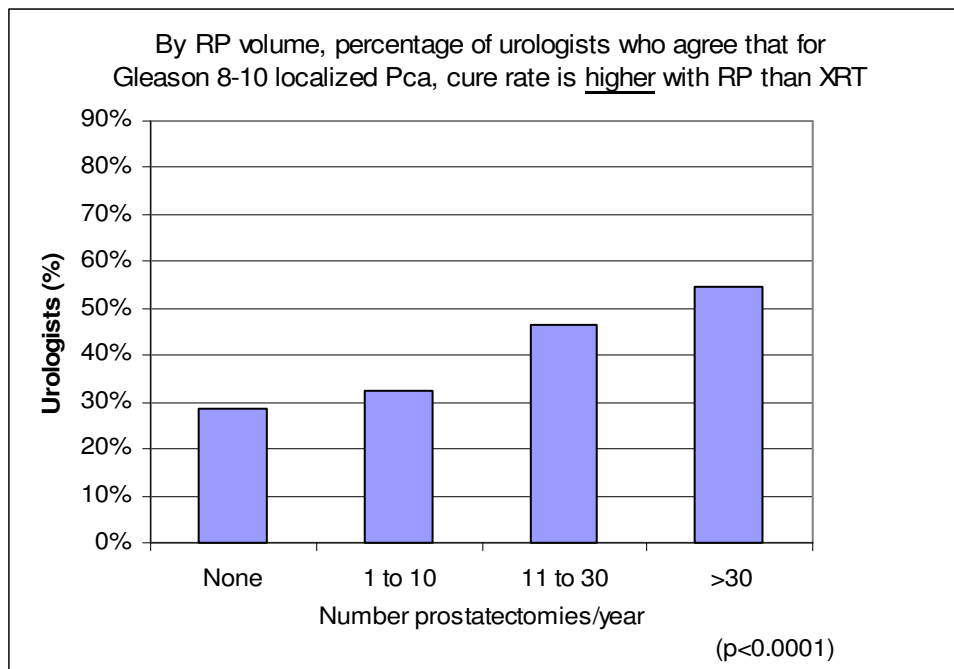
Cure rate higher with RP than XRT:

*endorsed by 40% overall and by 55% of urologists doing >30 RP's/year (+ association w/ volume)
best evidence, including PCOS, indicates that long-term survival is very similar between RP and XRT.*^{23 24}

Initial variables: numprost, academic, region, fellowship

	OR (95% CI)
Number of Prostatectomies per year	
1-10 vs. None	1.19 (0.78-1.82)
11-30 vs. None	2.16 (1.44-3.26)*
>30 vs. None	3.03 (1.88-4.88)*

Conclusion: Cure is the most important outcome for most patients. A large minority (40%) of urologists endorse the idea that RP is better than XRT for cure, and a majority (55%) of urologists who perform greater than 30 RP's/year make this claim. The claim is not supported by the evidence.



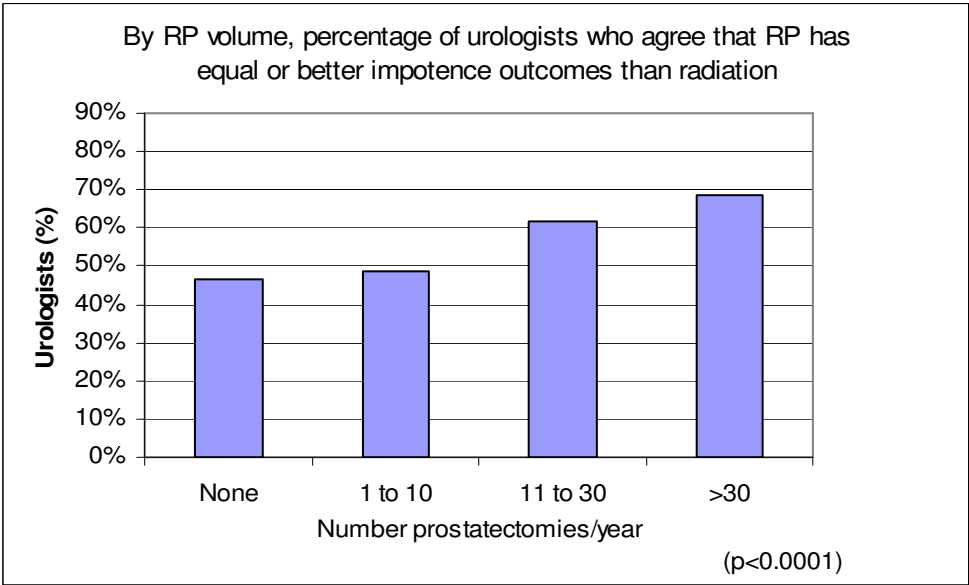
6. RP VS. ECBR IN TERMS OF IMPOTENCE

RP has equal or better long-term impotence outcomes than ECBR:
endorsed by 57% of urologists overall; by 48% of urologists doing <30 and 68% of urologists doing >30 RP's/year (+ association w/ volume)
in fact, best available evidence indicates that long-term impotence outcomes are very similar or slightly higher with ECBR..²³⁻²⁵ Potosky (2004) 5-year PCOS data show impotence (no erection for intercourse, as in our survey item) worse for RP than ECBR (79.3% vs. 63.5%). **Note – need to reconcile/explain why RP impotence in this 5yr PCOS report are higher than in the Penson report.**

Initial variables: numprost, >60% NHW, academic, population, bedsize, years_prac, fellowship

	OR (95% CI)
Number of Prostatectomies per year	
1-10 vs. None	0.97 (0.65-1.45)
11-30 vs. None	1.59 (1.05-2.33)*
>30 vs. None	1.96 (1.22-3.23)*
Academic	1.72 (1.04-2.86)*
Number of years practicing urology	
10-19 yrs vs. 0-9 yrs	0.79 (0.56-1.11)
20-29 yrs vs. 0-9 yrs	0.64 (0.46-0.89)*
30+ yrs vs. 0-9 yrs	0.64 (0.44-0.93)*

Conclusion: Greater procedure volume, academic practice, and fewer years practicing urology were associated with more frequently favorable comparisons between RP and ECBR in terms of potency outcomes. **Interpretation...**



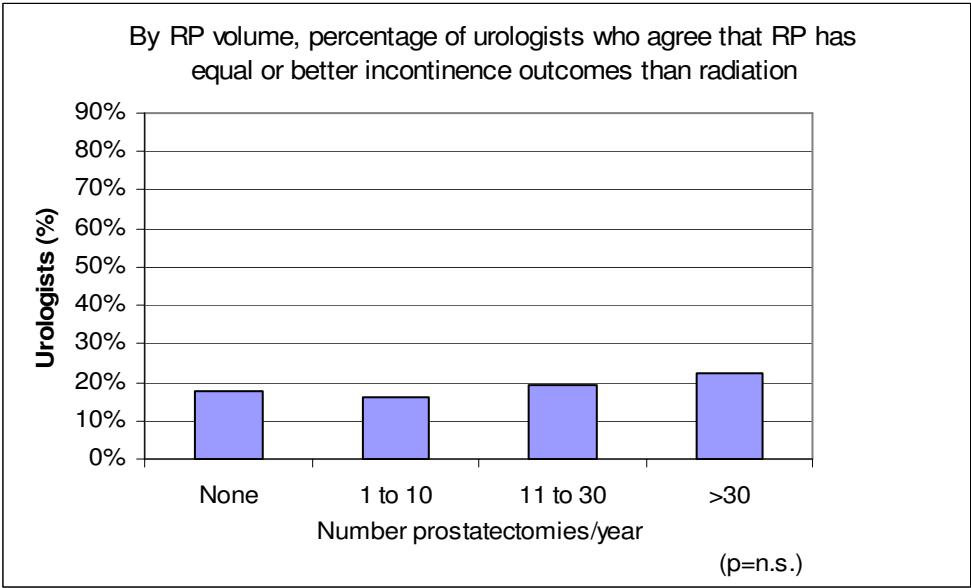
7. RP VS. ECBR IN TERMS OF INCONTINENCE

RP has equal or better long-term incontinence outcomes than ECBR:
endorsed by 20% overall (1 in 5 urologists); no association w/ surgical volume.
best available evidence indicates that incontinence outcomes tend to be much better on average w/ ECBR
PCOS²³: 5-year any pad = 29% (RP) vs. 4% (ECBR); and for other interpretations of incontinence, OR is 4.4 (2.2-8.6) for RP vs ECBR – “greater than occasional leakage”, and OR is 6.5 (2.7-15.6) “bothered by dripping/leaking urine”. Thus for any of the most conceivable interpretations of incontinence, ECBR clearly has better outcomes.

Initial variables: numprost, >60% NHW, academic, region

	OR (95% CI)
Number of Prostatectomies per year	
1-10 vs. None	0.88 (0.53-1.45)
11-30 vs. None	1.09 (0.67-1.75)
>30 vs. None	1.35 (0.77-2.33)

Conclusion: 20% of urologists believe incontinence outcomes are better w/ RP than ECBR —this may be a “problem” -- 20% is a sizable proportion and the differences in incontinence outcomes between RP and ECBR are quite large.



OVERALL CONCLUSIONS:

- A majority of urologists claim that RP has lower long-term rates of impotence and incontinence than is supported by evidence derived from larger community/multi-institutional series that use patient-reported measures. Caveat about interpretation of “any” incontinence.
- A majority of urologists, most of whom are in community practices and perform fewer than 2.5 RP’s/month, with over 40% of these performing fewer than 1/month, claim that their own rates of urinary and sexual side effects are lower than what is supported by the evidence. Caveat about interpretation of “any” incontinence.
- A sizable minority (39%) of high-volume urologists rate their potency outcomes better than what they perceive to be national averages – this claim may be reasonable but there is, thus far, no published evidence that clearly supports it.
- A large minority (44%) of low-volume urologists and a large majority (81%) of high-volume urologists rate their continence outcomes better than what they perceive to be a national average. Again, this Lake Wobegon effect is not (yet) supported by evidence.
- Cure is typically the most important outcome for patients. 40% of all urologists, and 55% of high-volume urologists, believe that rates of cure are better with RP than XRT, but the existing evidence does not support this.
- High volume urologists were significantly more likely than low volume urologists to compare RP favorably against ECBR in terms of potency outcomes.
- A sizable proportion (20%) of urologists believe incontinence outcomes are better w/ RP than ECBR — in fact, ECBR has significantly better incontinence outcomes.

→ A significant proportion of urologists manifest unsupported optimism about RP side effects in general, about their *own* side effect outcomes, and about the side effects and potential for cure of RP in relation to XRT. We found many of these patterns to be more pronounced among urologists who perform greater numbers of RP’s.

Discuss where academic and years in practice were predictors, and implications... Mention that academic and fellowship not predictors where one might have expected them to be... Lake Wobegon least pronounced in terms of perceptions of one’s own potency outcomes.

Important to clarify key issues:

- Urologists are not dishonest or disingenuous.
- These results should in no way be construed as an argument *against* RP, or *in favor* of a form of radiation. Rather, this is a study that compares urologist beliefs with the most recently published RP-associated outcomes. Knowledge of this evidence is important for patients in terms of decision-making -- they have to weigh treatment alternatives in light of personal preferences and values. It may be helpful for patients to know that a significant proportion of the time their physicians (in this case urologists) might quote side effect risks that are lower than what the evidence demonstrated from community studies with patient-reported measures. Patients should not assume that this will be true of any individual urologist, but these findings do highlight the importance of seeking information from more than one source.
- Urologists are no different than other types of specialists – they value and are biased towards the interventions they, themselves, provide.²⁶ If this survey had been given to radiation oncologists, the results would probably have been similar in terms of XRT.
- An important question is where urologists get their long-term outcome information. I would argue that older data and data from single-center series are a likely source. Because PCOS and other data are new, it is likely that many, if not most, urologists are unfamiliar with it.
- Although there may be controversy about PCOS it is hard to discount the idea that patient-reported outcomes in a comprehensive, longitudinal, community-based sample are more realistic than urologist-reported and -interpreted outcomes from earlier or single-center series.
- In terms of assessing one’s own outcomes, it is unusual for urologists to see a large fraction of their patients five years out from surgery. And, even if urologists do see patients five years out, patients may not be forthcoming about their symptoms. Both of these factors will limit urologists’ ability to accurately gauge their own long-term outcomes.

Three goals: (1) educate urologists about the latest outcome data so that they use it in discussions with patients (or at least tell patients that there is controversy, and then mention ranges of risk that include this data); community urologists, in particular, may have less justification for quoting results from single-center series; (2) reinforce to patients the importance of seeking information from more than one source; (3) carry out more studies of surgical volume relationships to impotence and incontinence outcomes; (4) be clear about definitions of “impotence” and “incontinence” (urinary and sexual function) in discussions with patients; be clear that each of these is a multi-dimensional construct.

Limitations: Although responders and non-responders very similar across all sociodemographic and clinical practice characteristics for which we had data, cannot exclude possibility of response bias, in which responders are more likely than non-responders to report favorable side effect outcomes. Ambiguity in item about incontinence. Does not directly ascertain the ways in which urologists actually present risk information to patients. **Details more...**

References:

1. Quinlan DM, Epstein JI, Carter BS, Walsh PC. Sexual function following radical prostatectomy: influence of preservation of neurovascular bundles. *J Urol* 1991;145(5):998-1002.
2. Walsh PC. Radical prostatectomy, preservation of sexual function, cancer control. The controversy. *Urol Clin North Am* 1987;14(4):663-73.
3. Catalona WJ, Basler JW. Return of erections and urinary continence following nerve sparing radical retropubic prostatectomy. *J Urol* 1993;150(3):905-7.
4. Feldman-Stewart D, Brundage MD, Hayter C, Davidson JR, Groome P, Nickel JC. What the prostate cancer patient should know: variations in urologists' opinions. *Can J Urol* 1997;4(4):438-444.
5. Penson DF, McLerran D, Feng Z, Li L, Albertsen PC, Gilliland FD, et al. 5-year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study. *J Urol* 2005;173(5):1701-5.
6. Stanford JL, Feng Z, Hamilton AS, Gilliland FD, Stephenson RA, Eley JW, et al. Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer: the Prostate Cancer Outcomes Study. *Jama* 2000;283(3):354-60.
7. Cooperberg MR, Koppie TM, Lubeck DP, Ye J, Grossfeld GD, Mehta SS, et al. How potent is potent? Evaluation of sexual function and bother in men who report potency after treatment for prostate cancer: data from CaPSURE. *Urology* 2003;61(1):190-6.
8. Fowler FJ, Jr., Barry MJ, Lu-Yao G, Roman A, Wasson J, Wennberg JE. Patient-reported complications and follow-up treatment after radical prostatectomy. The National Medicare Experience: 1988-1990 (updated June 1993). *Urology* 1993;42(6):622-9.
9. Kao TC, Cruess DF, Garner D, Foley J, Seay T, Friedrichs P, et al. Multicenter patient self-reporting questionnaire on impotence, incontinence and stricture after radical prostatectomy. *J Urol* 2000;163(3):858-64.
10. Leandri P, Rossignol G, Gautier JR, Ramon J. Radical retropubic prostatectomy: morbidity and quality of life. Experience with 620 consecutive cases. *J Urol* 1992;147(3 Pt 2):883-7.
11. Geary ES, Dendinger TE, Freiha FS, Stamey TA. Nerve sparing radical prostatectomy: a different view. *J Urol* 1995;154(1):145-9.
12. Schover LR, Fouladi RT, Warneke CL, Neese L, Klein EA, Zippe C, et al. Defining sexual outcomes after treatment for localized prostate carcinoma. *Cancer* 2002;95(8):1773-85.
13. Zippe CD, Jhaveri FM, Klein EA, Kedia S, Pasqualotto FF, Kedia A, et al. Role of Viagra after radical prostatectomy. *Urology* 2000;55(2):241-5.
14. Sebesta M, Cespedes RD, Luhman E, Optenberg S, Thompson IM. Questionnaire-based outcomes of urinary incontinence and satisfaction rates after radical prostatectomy in a national study population. *Urology* 2002;60(6):1055-8.
15. Anastasiadis AG, Salomon L, Katz R, Hoznek A, Chopin D, Abbou CC. Radical retropubic versus laparoscopic prostatectomy: a prospective comparison of functional outcome. *Urology* 2003;62(2):292-7.
16. Geary ES, Dendinger TE, Freiha FS, Stamey TA. Incontinence and vesical neck strictures following radical retropubic prostatectomy. *Urology* 1995;45(6):1000-6.
17. Hautmann RE, Sauter TW, Wenderoth UK. Radical retropubic prostatectomy: morbidity and urinary continence in 418 consecutive cases. *Urology* 1994;43(2 Suppl):47-51.
18. Hu JC, Elkin EP, Pasta DJ, Lubeck DP, Kattan MW, Carroll PR, et al. Predicting quality of life after radical prostatectomy: results from CaPSURE. *J Urol* 2004;171(2 Pt 1):703-7; discussion 707-8.
19. Hu JC, Gold KF, Pashos CL, Mehta SS, Litwin MS. Role of surgeon volume in radical prostatectomy outcomes. *J Clin Oncol* 2003;21(3):401-5.

20. Begg CB, Riedel ER, Bach PB, Kattan MW, Schrag D, Warren JL, et al. Variations in morbidity after radical prostatectomy. *N Engl J Med* 2002;346(15):1138-44.
21. Catalona WJ, Carvalhal GF, Mager DE, Smith DS. Potency, continence and complication rates in 1,870 consecutive radical retropubic prostatectomies. *J Urol* 1999;162(2):433-8.
22. Hollenbeck BK, Dunn RL, Wei JT, Montie JE, Sanda MG. Determinants of long-term sexual health outcome after radical prostatectomy measured by a validated instrument. *J Urol* 2003;169(4):1453-7.
23. Potosky AL, Davis WW, Hoffman RM, Stanford JL, Stephenson RA, Penson DF, et al. Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the prostate cancer outcomes study. *J Natl Cancer Inst* 2004;96(18):1358-67.
24. Jani AB, Hellman S. Early prostate cancer: clinical decision-making. *Lancet* 2003;361(9362):1045-53.
25. Litwin MS, Flanders SC, Pasta DJ, Stoddard ML, Lubeck DP, Henning JM. Sexual function and bother after radical prostatectomy or radiation for prostate cancer: multivariate quality-of-life analysis from CaPSURE. Cancer of the Prostate Strategic Urologic Research Endeavor. *Urology* 1999;54(3):503-8.
26. Fowler FJ, Jr., McNaughton Collins M, Albertsen PC, Zietman A, Elliott DB, Barry MJ. Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer. *Jama* 2000;283(24):3217-22.